Submitter : Mrs. Jeannie Terry **Date:** 04/26/2005

Organization : West Michigan Regional Cancer and Blood Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

From everything that I have read about the CAP/MVI program, I feel that our patients may suffer from an unproven system. Listed below are the reasons that I feel this program will not work.

MVI/CAP will be implemented without any testing or analysis of what is a radical change in the cancer care drug delivery system.

To substitute this proven delivery system with a concept that has not been tested is very dangerous.

MVI/CAP introduces a middleman between the sacred patient/physician relationship, because it will be the vendor dealing with the patient for the Medicare co-insurance drug payment. This is very dangerous as it can compromise the integrity of the medication, i.e. in looking for best pricing, a vendor can unknowingly acquire counterfeit and/or improperly stored medication which may cause harm to the patient.

Cancer Centers operating in rural areas do not have early morning guaranteed delivery times from FedEx, therefore causing a further delay in treatment, as many treatments are several hours long and must begin in the morning.

CMS has not addressed the bad debt that community cancer clinics carry relating to co-insurance payments that are not covered.

There may be difficulty in continuing treatments if a patient drug did not arrive because the patient fell behind in co-payments

Multiple vendors may be supplying drugs that go into a treatment regimen, thus creating a logistical nightmare.

Patients will be inconvenienced and have to return for treatment (new or switched) because new drugs will have to be ordered.

There will be increased drug wastage when treatments are held due to low counts or side effects

There will be increased drug wastage due to lack of drug stability when patients miss appointments

Increased difficulty in scheduling patients following restaging; i.e.: inability to quickly change chemotherapy regimens due to progression or no response.

We have the responsibility for the costly disposal of toxic chemotherapeutic waste

The impracticality of keeping multiple, patient specific drug inventories.

The program does not look at the overall cost of delivering quality cancer care

Submitter : Ms. Katherine Grigsby **Date:** 04/26/2005

Organization : Oncology Consultants, P.A.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

I am writing this comment on behalf of a private community oncology group in the Houston Texas area. I want to comment on the Medicare Outpatient Drugs and Biological Program Docket ID CMS-1325-P.

First I would ask that the pricing for ASP be revisited where some of the reimbursement rates of ASP are lower then these drugs can be purchased by local community oncology practices.

I would also ask for the Administration side of Oncology to be reevaluated. We are treating patient with Cancer not a cold or some minor illness that is cured in a few visit. However, our physicians get paid the same amount as other specialties and our nurses receive no reimbursement. Cancer patient demand an increase amount of time and resources to be care for properly. At this time the E&M codes do not take the amount of management and time nurses and physicians provided for treating the Cancer patient.

Another issue is for pharmacy facilities the ASP does not take into account the real cost of inventory and delivering the drugs to the patient.

On the idea of CAP our practices like many community oncology groups have spent time and many $$$ with inventory machines to keep up with our drugs. CAP starts a whole new process and would be very disruptive to our patients. This idea of shipping drugs into practices is reinventing the wheel when we already have a great and wonderful procedure in place to deliver drugs to cancer patients. Why are we starting a new process why not work with one that is already in place?

Last, I would like to request that the demonstration project be renew towards 2006 and refine to be a real model of quality model in Oncology. For years our providers have kept important records and maintained information regarding our Cancer patient that in working together as a team we can use and collect the date to assure quality cancer care in this country.

Thank you for taking the time in reading these comments and concerns.

Submitter : **Ms. Maya Bermingham** **Date: 04/26/2005**

Organization : **PhRMA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-433-Attach-1.PDF

PhRMA

April 26, 2005

VIA E-MAIL

http://www.cms.hhs.gov/regulations/ecomments
Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: **CMS-1325-P; Comments Regarding the Competitive Acquisition Program Proposed Rule**

Dear Dr. McClellan:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Competitive Acquisition Program (CAP) proposed rule issued by the Centers for Medicare and Medicaid Services (CMS).[1] PhRMA is a voluntary, nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA appreciates the thoughtful effort that went into developing the proposed rule, and believes CAP can enhance patients' access to appropriate medications by giving physicians the option of furnishing Part B drugs to their patients without having to engage in purchasing and billing activities or take into account financial issues. Our comments focus on ensuring that CAP is successful in facilitating appropriate patient care, and are based on the following principles:

- CAP should be implemented in a manner that respects physicians' medical judgments and improves their ability to offer patients the most medically appropriate drug therapies, thereby enhancing patient access;

- To encourage physician participation, CAP should be designed to minimize burdens on physicians, assure their confidence in the integrity of the products delivered by CAP vendors, and avoid restrictions on physician choices (including

[1] Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed rule, 70 Fed. Reg. 10746 (March 4, 2005).

the choice of purchasing and billing for any Part B drugs patients need that are not available through CAP); and

- To maximize participation both by physicians and prospective vendors, CAP should be carried out in accordance with clearly-defined, transparent rules (including roll-out timelines) informed by input from all of the program's stakeholders.

Our detailed comments on specific provisions in the proposed rule are set out below.

* * *

A. Categories of Drugs to be Included under CAP; Competitive Acquisition Areas

1. Permanently Limiting CAP to Physician-Administered Drugs

The Medicare Prescription Drug, Improvement and Modernization Act (the MMA) requires CMS to establish categories of competitively biddable drugs and biologicals that will be included in CAP. The MMA defines "competitively biddable drugs and biologicals" as drugs or biologicals described in section 1842(o)(1)(C) of the Social Security Act (SSA) and furnished on or after January 1, 2006.[2] As the proposed rule notes, the statutory definition includes "drugs administered incident to a physician's service (for example, drugs commonly furnished by oncologists), drugs administered through DME (for example, inhalation drugs), with the exception of DME infusion drugs, and some drugs usually dispensed by pharmacies (for example, oral immunosuppressive drugs)."[3]

The proposed rule would permanently limit the scope of CAP to physician-administered Part B drugs.[4] Given the challenges associated with implementing CAP, we believe limiting the program to physician-administered drugs during the phase-in period is a prudent measure that will facilitate a smooth implementation process. Nevertheless, we believe it would be premature to foreclose the possibility of expanding CAP to additional Part B drugs prior to the program's implementation and without the benefit of information and experience from the phase-in period. PhRMA therefore encourages CMS to leave open the possibility of extending CAP to the full range of "competitively biddable drugs," as defined in the MMA, once the phase-in experience provides a foundation for evaluating the feasibility of such an expansion. This approach seems most faithful to the statutory language, and could further Congress' goal of creating an alternative program that removes financial considerations from decisions by Medicare providers (including pharmacies as well as physicians).

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2 SSA § 1847B(a)(2)(A).

3 70 Fed. Reg. at 10749.

4 See proposed 42 C.F.R. § 414.902 (defining a "competitively biddable" drug as "a physician-administered drug or biological furnished on or after January 1, 2006 described in [SSA] section 1842(o)(1)(C)").

2. Phase-In Issues: Drug Categories and Competitive Acquisition Areas

The proposed rule describes several options for limiting CAP's scope during the initial phase-in period, both by drug category and geographic area. We believe an initial roll-out that encompasses all physician-administered Part B drugs in a limited number of state-wide competitive acquisition areas achieves the appropriate balance between the various goals CMS has articulated for the phase-in period. This approach would permit a focused, smaller-scale implementation effort, while also allowing CMS to identify the issues and concerns relevant to all of the physician specialties that administer Part B drugs. A geographical phase-in that includes all physician-administered drugs will enable CMS to identify issues representative of a full-scale CAP program in a smaller, more controlled environment, keeping the program manageable as CMS irons out identified issues and prepares for nation-wide implementation.

Moreover, we believe that for several reasons state-wide competitive acquisition areas provide the best opportunity for successful CAP implementation. State-defined CAP areas would maximize competition among vendors, by allowing smaller companies to enter the market and ensuring that state licensing laws or distribution networks corresponding to state boundaries do not create barriers to participation in CAP by smaller vendors. At the same time, this approach should also attract participation by larger national or regional vendors with the capability of serving a broader area and an interest in reaching a larger marketplace, because such vendors could submit bids for all or a subset of the state-wide areas included in the phase-in effort.

B. Claims Processing Overview

1. Physician Choice in Prescribing Appropriate Therapies

The MMA requires that physicians make an annual election about whether to participate in CAP.[5] The proposed rule clarifies that participating physicians may still obtain Part B drugs for their patients outside CAP, and receive reimbursement at 106% of Average Sales Price (ASP), in two circumstances.

The first circumstance involves "furnish as written" situations, where a participating physician's CAP vendor offers a drug (or drugs) within a certain HCPCS code, but the physician decides that a patient needs another drug falling within that HCPCS code that is not available through the CAP vendor. Specifically, the proposed rule provides that "in 'furnish as written' situations, when the physician has determined that it is medically necessary to use another brand of product within the HCPCS [code] or a product with an NDC that is not being furnished by the vendor . . . the physician would be allowed to bill for the drug under ASP, even though he or she had elected to participate in the CAP."[6] The proposed rule would require physicians to include a "furnish as written" modifier on such claims, and states that a Medicare carrier could deny such a

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[5] SSA § 1847B(a)(1)(A)(ii).

[6] 70 Fed. Reg. at 10756.

claim if it "determined that the physician had not complied with furnish as written requirements and that a specific NDC or brand name drug was not medically necessary."[7]

CMS proposed that participating physicians could also receive reimbursement at 106% of ASP for "those drugs not included in the CAP, and for drug categories that the physician does not select."[8] CMS has requested comments "on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or should be allowed to choose the categories [of] drugs he wishes to obtain from the vendor."[9]

PhRMA commends CMS for providing physicians who participate in CAP with the flexibility to choose appropriate therapies for their patients. This flexibility is critical to CAP's successful implementation, and will encourage physicians to participate in the program. Therefore, we strongly support CMS' proposal to allow physicians to select the specific categories of drugs they wish to receive from CAP vendors. Similarly, we encourage CMS to clarify that physicians could elect to obtain different categories of CAP drugs from different CAP vendors. In addition to encouraging physician participation in CAP, providing physicians with these choices will help to ensure that patients continue to have access to the drug therapies they need and will spur competition among CAP vendors to attract physician participation.

PhRMA also strongly supports the "furnish as written" proposal. However, the "furnish as written" billing system must operate in a way that does not impose unnecessary administrative burdens on physicians. While we support the medically necessary concept underlying the furnish as written proposal, we believe that physicians are in the best position to identify the drugs that are medically necessary for their individual patients, and should therefore be able to obtain non-CAP drugs for their patients through the least burdensome process possible. Thus, we recommend allowing physicians to bill for drugs not available through their CAP vendors using the normal procedures for submitting Part B claims, and assuring physicians that their judgments about medical necessity will not be "second-guessed" in these situations. This is important to ensure that physicians understand that CAP participation will not impinge in any way on their ability to treat patients in accordance with their best medical judgments, and feel no pressure to forego more appropriate treatments in favor of CAP drugs. Moreover, if CAP works as intended, the reduced administrative burden will give physicians a significant incentive to use CAP drugs when therapeutically appropriate for the individual patient.

2. Resupplying in Emergency Situations

The MMA requires CMS to establish rules that allow physicians to resupply their inventories with drugs supplied by CAP vendors when: (1) the drugs are required immediately; (2) the physicians could not have "reasonably anticipated" the immediate need for the drugs; (3) the CAP vendor could not deliver the drugs in a timely manner; and (4) the drugs were

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7 Id.

8 70 Fed. Reg. at 10755.

9 Id.

administered in an "emergency situation."[10] CMS has requested comments regarding the definition of "emergency situation."

Defining an "emergency situation" appropriately will be important in encouraging physician participation and ensuring CAP's success. Given the very nature of physician-administered drugs, there are many cases where the need for immediate administration of a drug only becomes apparent when the physician examines the patient. Similarly, the patient may come in for a previously-scheduled treatment, but examination of the patient may reveal the need for an immediate adjustment in the planned course of treatment. Without a process to accommodate these kinds of situations and provide patients with prompt access to needed drug therapies, physicians may decline to participate in CAP or patient care may be compromised by delayed or sub-optimal treatment. Therefore, PhRMA encourages CMS to adopt a flexible definition of "emergency situation" that is broad enough to encompass the array of circumstances where an immediate, unanticipated need for a particular drug may arise.

3. Assuring Patient Access to Unique Therapies that Share a HCPCS Code

The MMA requires CMS to conduct a competition in the case of multiple source drugs "for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[11] Under the proposed rule, CAP vendors would be required to provide drugs within each HCPCS code in a particular category.[12] We strongly support this principle, which is essential to encouraging physician participation in CAP.

However, the proposed rule also states that CAP vendors "will not be required to provide every National Drug Code [NDC] associated with a HCPCS code."[13] This could severely restrict the choices physicians need, and reduce CAP's utility, in those circumstances where different single-source drugs that are not generic equivalents are grouped together in the same HCPCS code.[14] Consequently, we urge CMS to clarify in the final rule that CAP vendors must provide at least one formulation (i.e., at least one NDC) for all single-source drugs that fall within the same HCPCS code. The fact that some single-source drugs share a HCPCS code does not mean that FDA has approved the products as therapeutically equivalent or bioequivalent, or that physicians will consider the different products equally appropriate for an individual patient; HCPCS codes

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[10] SSA § 1847B(b)(5).

[11] SSA § 1847B(b)(1). "Billing and payment codes" refers to HCPCS codes. See H. Rep. No. 108-391, at 594 (2003).

[12] 70 Fed. Reg. at 10751 (explaining that "if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all the HCPCS codes contained in the category," and that "[v]endors would not be able to submit bids on only some of the HCPCS codes in the category").

[13] 70 Fed. Reg. at 10751. This remark apparently involves only multiple-source drugs, since CMS cites proposed 42 C.F.R. § 414.908(d). That provision states that "[i]n the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one competitively biddable drug within each billing and payment code within each category for each competitive area."

[14] By "single-source" drugs, we mean: (1) a biological; or (2) a drug that is not a multiple source drug and that is distributed under a new drug application approved by the FDA. See SSA § 1847A(c)(6)(D).

were designed only for billing and payment purposes, not to represent medical determinations. Consequently, making clear that CAP vendors must supply at least one NDC for each of the single-source products within a given drug category would establish an important safeguard that will help to ensure patients receive the most appropriate medication and will expand the choices available to physicians under CAP, thus reducing the need to purchase drugs outside the program pursuant to the "furnish as written" procedures. Similarly, CMS should emphasize that Congress created CAP to give physicians a viable, appealing alternative to the ASP-based reimbursement system, and did not authorize CAP vendors to undermine that goal by constructing restrictive lists that would discourage physicians from participating in CAP.

4. Coverage Issues

Under CAP, vendors are responsible for delivering drugs to physicians in a timely manner.[15] In the proposed rule, CMS noted that physicians and their carriers will be responsible for checking to determine whether competitively biddable drugs are used consistently with any Local Coverage Determinations.[16] Similarly, the proposed rule makes clear that denied claims for administration services associated with CAP drugs will be handled under Medicare's appeals process. However, the proposed rule does not expressly state that CAP vendors may not analyze coverage issues before filling physicians' orders for drugs. We urge CMS to clarify in the final rule that CAP vendors may not withhold a drug or biological they contracted to supply based upon their own "coverage determination." CMS should emphasize that CAP will not modify Medicare's existing rules on coverage of off-label uses,[17] or modify Medicare's existing processes for determining whether a particular claim is covered. CAP vendors cannot be permitted to short-circuit carriers' coverage decisions (or the appeals process for denied claims) by failing to supply drugs ordered by participating physicians because the vendor believes the claim could be denied; making decisions about coverage issues is not among the vendors' authorized functions.

5. Supplying Patient Information to CAP Vendors

The proposed rule lists various items of information that physicians would be required to include in their orders to CAP vendors, most of which seem necessary for filling the order or for the vendor's billing purposes. However, the information also would include "Additional Patient Info: date of birth, allergies, Ht/Wt/ICD-9, etc."[18] The rationale for this category is not clear. Height and weight information would not be needed by the CAP vendor, because the physician determines the dosage needed by the patient and lists this on the order. Any diagnostic or similar information needed to determine whether the drug and the associated administration services were covered would be provided by the physician to his or her local carrier, in the claim for the

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15 SSA § 1847B(b)(2)(A)(i)(II).

16 70 Fed. Reg. at 10756.

17 See Medicare Benefit Policy Manual § 50.4.2 (carriers may cover off-label uses of a drug "if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice"); § 50.4.5 (medically accepted indications for anti-cancer drugs include off-label uses supported by specified compendia or peer-reviewed journal articles, or "determined by the carrier to be medically accepted generally as safe and effective").

18 70 Fed. Reg. at 10756.

drug administration services; the carrier's decision on that claim would then determine coverage of the drug itself. Thus, there seems to be no reason for requiring that physicians supply this type of patient information to CAP vendors. We would encourage CMS to eliminate this proposed requirement.

C. Contracting Process - Quality and Product Integrity Aspects

PhRMA commends CMS' efforts to ensure that "reputable, and experienced vendors are chosen to participate in the CAP" and the proposed rule's emphasis on ensuring product integrity.[19] We fully support CMS' proposal to impose appropriate product integrity and quality standards, and to suspend or terminate a vendor's contract if that vendor fails to comply with any of these standards. We believe requiring strict compliance with quality and product integrity standards is essential both for patient safety and for establishing a successful CAP program. PhRMA looks forward to working with CMS to ensure that these important standards are met.

D. CAP Bidding Process - - Evaluation and Selection

1. Imposing a Composite Bid Ceiling

Under the proposed rule, bidders eligible for selection as CAP vendors would only include those whose "composite bids" did not exceed a specified ceiling (i.e., 106% of the weighted ASP for the drugs in that particular category).[20] This ceiling is not required or authorized by the MMA, and it conflicts with CAP's underlying market-based philosophy. While Congress hoped that CAP would generate cost savings (though, as CMS correctly notes, this is not the program's only goal[21]), Congress selected the market mechanism as the vehicle to reduce costs under CAP. Consequently, we would encourage CMS to embrace that same philosophy and rely on market forces to contain costs, structuring CAP to promote broad participation by potential vendors and robust competition.

By avoiding price ceilings, CMS would also assure that bidders lacked any incentive to de-emphasize quality, product integrity and customer service efforts; avoid the complexities associated with constructing an ASP-based composite ceiling (for example, the problem CMS noted with assigning a weighting to newer drugs not adequately reflected in the historical data); and allow the CAP program to serve a "safety valve" function in instances where the 106% of ASP payment rate might reduce access to a particular drug. We are concerned that the ASP-based payment system may not prove adequate to ensure patient access for all Part B drugs, which are critical therapies used to treat cancer and other serious diseases that must remain available to Medicare beneficiaries. Imposing price ceilings that prevent CAP from serving as a safety valve would needlessly increase the risk of compromised access to care, particularly as the cancer demonstration project credited with alleviating access problems under the ASP-based system might end in 2006.

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[19] 70 Fed. Reg. at 10759.

[20] 70 Fed. Reg. at 10763.

[21] 70 Fed. Reg. at 10748.

2. Post-award Price Adjustments

The MMA provides for: (1) periodic disclosures to CMS (not more often than quarterly) of vendors' "reasonable, net acquisition costs" for CAP drugs; and (2) appropriate price adjustments over the three-year contract term to reflect significant increases or decreases in vendors' disclosed acquisition costs.[22] Under the proposed rule, vendors would submit annual disclosures of their reasonable, net acquisition costs, and prices would generally be updated annually based on these disclosures.[23] While we recognize that CMS proposed this approach in order to limit the frequency and burden of the periodic cost disclosures, we would encourage CMS to consider quarterly cost disclosures and pricing updates. This approach would produce greater savings for CMS in instances where vendors' overall costs for CAP drugs were declining, while providing greater protection for vendors (and thus encouraging continued participation in CAP) in instances where vendors were experiencing cost increases. In addition, this approach would synchronize the timing of CAP payment updates and the payment updates under the ASP-based system.

3. Integrating New Drugs Into CAP

Under the MMA, CMS must establish rules regarding "the use under [CAP] of the alternative payment amount provided under [SSA] section 1847A" in setting CAP payments for new drugs without a HCPCS code.[24] SSA § 1847A(c)(4) provides for a temporary alternative payment based on: (1) wholesale acquisition cost (WAC); or (2) pre-MMA payment methodologies. CMS has implemented this provision by adopting a temporary payment rate equal to 106% of WAC for new drugs first sold on or after December 1, 2004.[25] Under the proposed CAP rule, CMS would apply the § 1847A(c)(4) payment rate to any new drug falling within a CAP category that requires the issuance of a new HCPCS code.[26] We believe this is an appropriate approach to setting a temporary payment rate for new drugs included in CAP, and recommend that CMS explicitly incorporate the 106% of WAC methodology it recently adopted into the CAP final rule.

We would also encourage CMS to develop a mechanism for ensuring that new drugs falling within a CAP category are promptly available from CAP vendors contracted to supply that category of drugs. For example, CMS might: (1) task its "designated carrier" for CAP claims to notify CAP vendors as soon as a new drug is introduced that falls within the category or categories they supply (as well as notifying vendors of the 106% of WAC payment amount for the new drug); and (2) include provisions in its CAP contracts obligating the vendor to begin filling orders for such new drugs, at a 106% of WAC payment rate, upon receipt of such a notification regarding a new drug within the vendor's category or categories.

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22 SSA § 1847B(c)(7).

23 70 Fed. Reg. at 10764-65.

24 SSA § 1847B(d)(2).

25 CMS Transmittal No. 480, § I.B(5) (Feb. 25, 2005).

26 70 Fed. Reg. at 10764. This payment rate would apply until the next update of CAP prices. Id.

To the extent that a new drug is not immediately available from a physician's CAP vendor, participating physicians should be able to purchase the drug from their usual commercial sources and receive reimbursement at 106% of ASP (or 106% of WAC, if CMS has not yet set an ASP-based payment for the drug). CMS should therefore incorporate provisions explicitly recognizing physicians' right to bill for new drugs that are not available from their CAP vendors in the CAP final rule.

4. Confidentiality of Pricing Information

As noted earlier, CAP vendors must periodically disclose their "reasonable, net acquisition costs" for drugs to CMS. The proposed rule requires annual disclosures that would "reflect the vendor's purchases of these [CAP] drugs from all manufacturers, and the total number of units purchased from each manufacturer."[27] The proposed rule also requires vendors to submit "full documentation reflecting these purchases, including contracts, invoices, and other agreements that reflect the actual purchase prices" and "all records reflecting discounts that result in a reduction of actual cost to the vendor" (e.g., volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, and refunds).[28] The proposed rule, however, does not include provisions concerning the confidentiality of this information.

The MMA addresses the confidentiality of pricing information provided to CMS by CAP vendors. The MMA authorizes CMS to waive provisions of the Federal Acquisition Regulation necessary for the efficient implementation of CAP "other than provisions relating to confidentiality of information," and further provides that the confidentiality provisions in SSA Section 1927(b)(3)(D) "shall apply to periods during which a bid is submitted with respect to a competitively biddable drug."[29] These MMA provisions indicate that Congress intended that pricing information provided to CMS by CAP vendors be treated as confidential. In addition, the confidentiality of the information CAP vendors supply to CMS in their periodic disclosures of net acquisition costs would also be protected by the Trade Secrets Act (18 U.S.C. § 1905). We encourage CMS to include appropriate confidentiality provisions consistent with these statutory mandates in the final CAP rule.

E. Ensuring Public Input and Transparency

PhRMA appreciates CMS' efforts to work with CAP stakeholders in developing and implementing the program. Given the significant amount of regulatory work that remains before CAP is implemented in January 2006, and the important details concerning CAP implementation that might ultimately be developed through subregulatory guidance, we hope that CMS will continue to provide ongoing opportunities for stakeholder input regarding the program. In implementing the Part D benefit, for example, CMS has frequently released subregulatory guidance on various aspects of Part D implementation in draft form and invited public comments before finalizing the guidance. This approach has worked well in fostering a dialogue between

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[27] 70 Fed. Reg. at 10765.

[28] Id.

[29] SSA § 1847B(a)(1)(C), (c)(5) (emphasis added).

CMS and the program's stakeholders, and we would encourage CMS to adopt a similar collaborative approach as it moves forward with CAP implementation. Such an approach will provide CMS with ongoing access to the broad range of information it needs to structure the program successfully, and help to ensure the transparency needed to maximize physician and vendor participation. Similarly, issuing the CAP final rule as an interim final rule with comment period would provide the opportunity for stakeholder input that could help CMS quickly identify regulatory changes that would improve CAP's effectiveness.

* * *

PhRMA hopes that these comments will be useful to CMS in crafting the CAP final rule and in implementing the program. We look forward to further dialogue on these issues and trust that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith,
Senior Vice President for
Policy, Research, and Strategic Planning

Bruce N. Kuhlik
Senior Vice President and
General Counsel

Submitter : Mr. Michael Sullivan, FACMPE **Date:** 04/26/2005

Organization : Northwest Medical Specialties

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Comments attached

CMS-1325-P-434-Attach-1.DOC

CMS-1325-P-434-Attach-2.DOC

Submitter : **Jeannie Hughes** **Date: 04/26/2005**

Organization : **Oncology Assoc of West KY**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on my concerns re: CAP for 2006. Billing within 14 days may be a problem on a small practice. Inventory for Medicare pts vs Commercial & Medicaid pts will be intensive. What about reimbursement for supplies used since no revenue from drugs. What if pt can't receive the tx? Who pays to send them back & what if they expire? What about timeliness of receiving the drugs? What about drugs ordered but are "off label" & denied? And can the wholesaler substitute drugs? What if CAP doesn't handle all the drugs in a tx regimen? Get from various sources?? Also being locked into a vendor for 1 yr is excessive. What about pt inconvenience? Need to fix ASP & continue the demo project. These are just a few of my concerns. Thanks

Submitter : **Ms. Maya Bermingham** **Date: 04/26/2005**

Organization : **PhRMA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1325-P-436-Attach-1.PDF

PhRMA

April 26, 2005

VIA E-MAIL

http://www.cms.hhs.gov/regulations/ecomments
Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: **CMS-1325-P; Comments Regarding the Competitive Acquisition Program Proposed Rule**

Dear Dr. McClellan:

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PhRMA appreciates the thoughtful effort that went into developing the proposed rule, and believes CAP can enhance patients' access to appropriate medications by giving physicians the option of furnishing Part B drugs to their patients without having to engage in purchasing and billing activities or take into account financial issues. Our comments focus on ensuring that CAP is successful in facilitating appropriate patient care, and are based on the following principles:

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[1] Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B; Proposed rule, 70 Fed. Reg. 10746 (March 4, 2005).

the choice of purchasing and billing for any Part B drugs patients need that are not available through CAP); and

- To maximize participation both by physicians and prospective vendors, CAP should be carried out in accordance with clearly-defined, transparent rules (including roll-out timelines) informed by input from all of the program's stakeholders.

Our detailed comments on specific provisions in the proposed rule are set out below.

* * *

A. Categories of Drugs to be Included under CAP; Competitive Acquisition Areas

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The proposed rule would permanently limit the scope of CAP to physician-administered Part B drugs.[4] Given the challenges associated with implementing CAP, we believe limiting the program to physician-administered drugs during the phase-in period is a prudent measure that will facilitate a smooth implementation process. Nevertheless, we believe it would be premature to foreclose the possibility of expanding CAP to additional Part B drugs prior to the program's implementation and without the benefit of information and experience from the phase-in period. PhRMA therefore encourages CMS to leave open the possibility of extending CAP to the full range of "competitively biddable drugs," as defined in the MMA, once the phase-in experience provides a foundation for evaluating the feasibility of such an expansion. This approach seems most faithful to the statutory language, and could further Congress' goal of creating an alternative program that removes financial considerations from decisions by Medicare providers (including pharmacies as well as physicians).

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2 SSA § 1847B(a)(2)(A).

3 70 Fed. Reg. at 10749.

4 See proposed 42 C.F.R. § 414.902 (defining a "competitively biddable" drug as "a physician-administered drug or biological furnished on or after January 1, 2006 described in [SSA] section 1842(o)(1)(C)").

2. Phase-In Issues: Drug Categories and Competitive Acquisition Areas

The proposed rule describes several options for limiting CAP's scope during the initial phase-in period, both by drug category and geographic area. We believe an initial roll-out that encompasses all physician-administered Part B drugs in a limited number of state-wide competitive acquisition areas achieves the appropriate balance between the various goals CMS has articulated for the phase-in period. This approach would permit a focused, smaller-scale implementation effort, while also allowing CMS to identify the issues and concerns relevant to all of the physician specialties that administer Part B drugs. A geographical phase-in that includes all physician-administered drugs will enable CMS to identify issues representative of a full-scale CAP program in a smaller, more controlled environment, keeping the program manageable as CMS irons out identified issues and prepares for nation-wide implementation.

Moreover, we believe that for several reasons state-wide competitive acquisition areas provide the best opportunity for successful CAP implementation. State-defined CAP areas would maximize competition among vendors, by allowing smaller companies to enter the market and ensuring that state licensing laws or distribution networks corresponding to state boundaries do not create barriers to participation in CAP by smaller vendors. At the same time, this approach should also attract participation by larger national or regional vendors with the capability of serving a broader area and an interest in reaching a larger marketplace, because such vendors could submit bids for all or a subset of the state-wide areas included in the phase-in effort.

B. Claims Processing Overview

1. Physician Choice in Prescribing Appropriate Therapies

The MMA requires that physicians make an annual election about whether to participate in CAP.[5] The proposed rule clarifies that participating physicians may still obtain Part B drugs for their patients outside CAP, and receive reimbursement at 106% of Average Sales Price (ASP), in two circumstances.

The first circumstance involves "furnish as written" situations, where a participating physician's CAP vendor offers a drug (or drugs) within a certain HCPCS code, but the physician decides that a patient needs another drug falling within that HCPCS code that is not available through the CAP vendor. Specifically, the proposed rule provides that "in 'furnish as written' situations, when the physician has determined that it is medically necessary to use another brand of product within the HCPCS [code] or a product with an NDC that is not being furnished by the vendor . . . the physician would be allowed to bill for the drug under ASP, even though he or she had elected to participate in the CAP."[6] The proposed rule would require physicians to include a "furnish as written" modifier on such claims, and states that a Medicare carrier could deny such a

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5 SSA § 1847B(a)(1)(A)(ii).

6 70 Fed. Reg. at 10756.

claim if it "determined that the physician had not complied with furnish as written requirements and that a specific NDC or brand name drug was not medically necessary."[7]

CMS proposed that participating physicians could also receive reimbursement at 106% of ASP for "those drugs not included in the CAP, and for drug categories that the physician does not select."[8] CMS has requested comments "on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or should be allowed to choose the categories [of] drugs he wishes to obtain from the vendor."[9]

PhRMA commends CMS for providing physicians who participate in CAP with the flexibility to choose appropriate therapies for their patients. This flexibility is critical to CAP's successful implementation, and will encourage physicians to participate in the program. Therefore, we strongly support CMS' proposal to allow physicians to select the specific categories of drugs they wish to receive from CAP vendors. Similarly, we encourage CMS to clarify that physicians could elect to obtain different categories of CAP drugs from different CAP vendors. In addition to encouraging physician participation in CAP, providing physicians with these choices will help to ensure that patients continue to have access to the drug therapies they need and will spur competition among CAP vendors to attract physician participation.

PhRMA also strongly supports the "furnish as written" proposal. However, the "furnish as written" billing system must operate in a way that does not impose unnecessary administrative burdens on physicians. While we support the medically necessary concept underlying the furnish as written proposal, we believe that physicians are in the best position to identify the drugs that are medically necessary for their individual patients, and should therefore be able to obtain non-CAP drugs for their patients through the least burdensome process possible. Thus, we recommend allowing physicians to bill for drugs not available through their CAP vendors using the normal procedures for submitting Part B claims, and assuring physicians that their judgments about medical necessity will not be "second-guessed" in these situations. This is important to ensure that physicians understand that CAP participation will not impinge in any way on their ability to treat patients in accordance with their best medical judgments, and feel no pressure to forego more appropriate treatments in favor of CAP drugs. Moreover, if CAP works as intended, the reduced administrative burden will give physicians a significant incentive to use CAP drugs when therapeutically appropriate for the individual patient.

2. Resupplying in Emergency Situations

The MMA requires CMS to establish rules that allow physicians to resupply their inventories with drugs supplied by CAP vendors when: (1) the drugs are required immediately; (2) the physicians could not have "reasonably anticipated" the immediate need for the drugs; (3) the CAP vendor could not deliver the drugs in a timely manner; and (4) the drugs were

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7 Id.

8 70 Fed. Reg. at 10755.

9 Id.

administered in an "emergency situation."[10] CMS has requested comments regarding the definition of "emergency situation."

Defining an "emergency situation" appropriately will be important in encouraging physician participation and ensuring CAP's success. Given the very nature of physician-administered drugs, there are many cases where the need for immediate administration of a drug only becomes apparent when the physician examines the patient. Similarly, the patient may come in for a previously-scheduled treatment, but examination of the patient may reveal the need for an immediate adjustment in the planned course of treatment. Without a process to accommodate these kinds of situations and provide patients with prompt access to needed drug therapies, physicians may decline to participate in CAP or patient care may be compromised by delayed or sub-optimal treatment. Therefore, PhRMA encourages CMS to adopt a flexible definition of "emergency situation" that is broad enough to encompass the array of circumstances where an immediate, unanticipated need for a particular drug may arise.

3. Assuring Patient Access to Unique Therapies that Share a HCPCS Code

The MMA requires CMS to conduct a competition in the case of multiple source drugs "for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category for each competitive acquisition area."[11] Under the proposed rule, CAP vendors would be required to provide drugs within each HCPCS code in a particular category.[12] We strongly support this principle, which is essential to encouraging physician participation in CAP.

However, the proposed rule also states that CAP vendors "will not be required to provide every National Drug Code [NDC] associated with a HCPCS code."[13] This could severely restrict the choices physicians need, and reduce CAP's utility, in those circumstances where different single-source drugs that are not generic equivalents are grouped together in the same HCPCS code.[14] Consequently, we urge CMS to clarify in the final rule that CAP vendors must provide at least one formulation (i.e., at least one NDC) for all single-source drugs that fall within the same HCPCS code. The fact that some single-source drugs share a HCPCS code does not mean that FDA has approved the products as therapeutically equivalent or bioequivalent, or that physicians will consider the different products equally appropriate for an individual patient; HCPCS codes

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[10] SSA § 1847B(b)(5).

[11] SSA § 1847B(b)(1). "Billing and payment codes" refers to HCPCS codes. See H. Rep. No. 108-391, at 594 (2003).

[12] 70 Fed. Reg. at 10751 (explaining that "if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all the HCPCS codes contained in the category," and that "[v]endors would not be able to submit bids on only some of the HCPCS codes in the category").

[13] 70 Fed. Reg. at 10751. This remark apparently involves only multiple-source drugs, since CMS cites proposed 42 C.F.R. § 414.908(d). That provision states that "[i]n the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one competitively biddable drug within each billing and payment code within each category for each competitive area."

[14] By "single-source" drugs, we mean: (1) a biological; or (2) a drug that is not a multiple source drug and that is distributed under a new drug application approved by the FDA. See SSA § 1847A(c)(6)(D).

were designed only for billing and payment purposes, not to represent medical determinations. Consequently, making clear that CAP vendors must supply at least one NDC for each of the single-source products within a given drug category would establish an important safeguard that will help to ensure patients receive the most appropriate medication and will expand the choices available to physicians under CAP, thus reducing the need to purchase drugs outside the program pursuant to the "furnish as written" procedures. Similarly, CMS should emphasize that Congress created CAP to give physicians a viable, appealing alternative to the ASP-based reimbursement system, and did not authorize CAP vendors to undermine that goal by constructing restrictive lists that would discourage physicians from participating in CAP.

4. Coverage Issues

Under CAP, vendors are responsible for delivering drugs to physicians in a timely manner.[15] In the proposed rule, CMS noted that physicians and their carriers will be responsible for checking to determine whether competitively biddable drugs are used consistently with any Local Coverage Determinations.[16] Similarly, the proposed rule makes clear that denied claims for administration services associated with CAP drugs will be handled under Medicare's appeals process. However, the proposed rule does not expressly state that CAP vendors may not analyze coverage issues before filling physicians' orders for drugs. We urge CMS to clarify in the final rule that CAP vendors may not withhold a drug or biological they contracted to supply based upon their own "coverage determination." CMS should emphasize that CAP will not modify Medicare's existing rules on coverage of off-label uses,[17] or modify Medicare's existing processes for determining whether a particular claim is covered. CAP vendors cannot be permitted to short-circuit carriers' coverage decisions (or the appeals process for denied claims) by failing to supply drugs ordered by participating physicians because the vendor believes the claim could be denied; making decisions about coverage issues is not among the vendors' authorized functions.

5. Supplying Patient Information to CAP Vendors

The proposed rule lists various items of information that physicians would be required to include in their orders to CAP vendors, most of which seem necessary for filling the order or for the vendor's billing purposes. However, the information also would include "Additional Patient Info: date of birth, allergies, Ht/Wt/ICD-9, etc."[18] The rationale for this category is not clear. Height and weight information would not be needed by the CAP vendor, because the physician determines the dosage needed by the patient and lists this on the order. Any diagnostic or similar information needed to determine whether the drug and the associated administration services were covered would be provided by the physician to his or her local carrier, in the claim for the

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15 SSA § 1847B(b)(2)(A)(i)(II).

16 70 Fed. Reg. at 10756.

17 See Medicare Benefit Policy Manual § 50.4.2 (carriers may cover off-label uses of a drug "if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice"); § 50.4.5 (medically accepted indications for anti-cancer drugs include off-label uses supported by specified compendia or peer-reviewed journal articles, or "determined by the carrier to be medically accepted generally as safe and effective").

18 70 Fed. Reg. at 10756.

drug administration services; the carrier's decision on that claim would then determine coverage of the drug itself. Thus, there seems to be no reason for requiring that physicians supply this type of patient information to CAP vendors. We would encourage CMS to eliminate this proposed requirement.

C. Contracting Process - Quality and Product Integrity Aspects

PhRMA commends CMS' efforts to ensure that "reputable, and experienced vendors are chosen to participate in the CAP" and the proposed rule's emphasis on ensuring product integrity.[19] We fully support CMS' proposal to impose appropriate product integrity and quality standards, and to suspend or terminate a vendor's contract if that vendor fails to comply with any of these standards. We believe requiring strict compliance with quality and product integrity standards is essential both for patient safety and for establishing a successful CAP program. PhRMA looks forward to working with CMS to ensure that these important standards are met.

D. CAP Bidding Process - - Evaluation and Selection

1. Imposing a Composite Bid Ceiling

Under the proposed rule, bidders eligible for selection as CAP vendors would only include those whose "composite bids" did not exceed a specified ceiling (i.e., 106% of the weighted ASP for the drugs in that particular category).[20] This ceiling is not required or authorized by the MMA, and it conflicts with CAP's underlying market-based philosophy. While Congress hoped that CAP would generate cost savings (though, as CMS correctly notes, this is not the program's only goal[21]), Congress selected the market mechanism as the vehicle to reduce costs under CAP. Consequently, we would encourage CMS to embrace that same philosophy and rely on market forces to contain costs, structuring CAP to promote broad participation by potential vendors and robust competition.

By avoiding price ceilings, CMS would also assure that bidders lacked any incentive to de-emphasize quality, product integrity and customer service efforts; avoid the complexities associated with constructing an ASP-based composite ceiling (for example, the problem CMS noted with assigning a weighting to newer drugs not adequately reflected in the historical data); and allow the CAP program to serve a "safety valve" function in instances where the 106% of ASP payment rate might reduce access to a particular drug. We are concerned that the ASP-based payment system may not prove adequate to ensure patient access for all Part B drugs, which are critical therapies used to treat cancer and other serious diseases that must remain available to Medicare beneficiaries. Imposing price ceilings that prevent CAP from serving as a safety valve would needlessly increase the risk of compromised access to care, particularly as the cancer demonstration project credited with alleviating access problems under the ASP-based system might end in 2006.

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[19] 70 Fed. Reg. at 10759.

[20] 70 Fed. Reg. at 10763.

[21] 70 Fed. Reg. at 10748.

2. Post-award Price Adjustments

The MMA provides for: (1) periodic disclosures to CMS (not more often than quarterly) of vendors' "reasonable, net acquisition costs" for CAP drugs; and (2) appropriate price adjustments over the three-year contract term to reflect significant increases or decreases in vendors' disclosed acquisition costs.[22] Under the proposed rule, vendors would submit annual disclosures of their reasonable, net acquisition costs, and prices would generally be updated annually based on these disclosures.[23] While we recognize that CMS proposed this approach in order to limit the frequency and burden of the periodic cost disclosures, we would encourage CMS to consider quarterly cost disclosures and pricing updates. This approach would produce greater savings for CMS in instances where vendors' overall costs for CAP drugs were declining, while providing greater protection for vendors (and thus encouraging continued participation in CAP) in instances where vendors were experiencing cost increases. In addition, this approach would synchronize the timing of CAP payment updates and the payment updates under the ASP-based system.

3. Integrating New Drugs Into CAP

Under the MMA, CMS must establish rules regarding "the use under [CAP] of the alternative payment amount provided under [SSA] section 1847A" in setting CAP payments for new drugs without a HCPCS code.[24] SSA § 1847A(c)(4) provides for a temporary alternative payment based on: (1) wholesale acquisition cost (WAC); or (2) pre-MMA payment methodologies. CMS has implemented this provision by adopting a temporary payment rate equal to 106% of WAC for new drugs first sold on or after December 1, 2004.[25] Under the proposed CAP rule, CMS would apply the § 1847A(c)(4) payment rate to any new drug falling within a CAP category that requires the issuance of a new HCPCS code.[26] We believe this is an appropriate approach to setting a temporary payment rate for new drugs included in CAP, and recommend that CMS explicitly incorporate the 106% of WAC methodology it recently adopted into the CAP final rule.

We would also encourage CMS to develop a mechanism for ensuring that new drugs falling within a CAP category are promptly available from CAP vendors contracted to supply that category of drugs. For example, CMS might: (1) task its "designated carrier" for CAP claims to notify CAP vendors as soon as a new drug is introduced that falls within the category or categories they supply (as well as notifying vendors of the 106% of WAC payment amount for the new drug); and (2) include provisions in its CAP contracts obligating the vendor to begin filling orders for such new drugs, at a 106% of WAC payment rate, upon receipt of such a notification regarding a new drug within the vendor's category or categories.

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22 SSA § 1847B(c)(7).

23 70 Fed. Reg. at 10764-65.

24 SSA § 1847B(d)(2).

25 CMS Transmittal No. 480, § I.B(5) (Feb. 25, 2005).

26 70 Fed. Reg. at 10764. This payment rate would apply until the next update of CAP prices. Id.

To the extent that a new drug is not immediately available from a physician's CAP vendor, participating physicians should be able to purchase the drug from their usual commercial sources and receive reimbursement at 106% of ASP (or 106% of WAC, if CMS has not yet set an ASP-based payment for the drug). CMS should therefore incorporate provisions explicitly recognizing physicians' right to bill for new drugs that are not available from their CAP vendors in the CAP final rule.

4. Confidentiality of Pricing Information

As noted earlier, CAP vendors must periodically disclose their "reasonable, net acquisition costs" for drugs to CMS. The proposed rule requires annual disclosures that would "reflect the vendor's purchases of these [CAP] drugs from all manufacturers, and the total number of units purchased from each manufacturer."[27] The proposed rule also requires vendors to submit "full documentation reflecting these purchases, including contracts, invoices, and other agreements that reflect the actual purchase prices" and "all records reflecting discounts that result in a reduction of actual cost to the vendor" (e.g., volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, rebates, and refunds).[28] The proposed rule, however, does not include provisions concerning the confidentiality of this information.

The MMA addresses the confidentiality of pricing information provided to CMS by CAP vendors. The MMA authorizes CMS to waive provisions of the Federal Acquisition Regulation necessary for the efficient implementation of CAP "other than provisions relating to confidentiality of information," and further provides that the confidentiality provisions in SSA Section 1927(b)(3)(D) "shall apply to periods during which a bid is submitted with respect to a competitively biddable drug."[29] These MMA provisions indicate that Congress intended that pricing information provided to CMS by CAP vendors be treated as confidential. In addition, the confidentiality of the information CAP vendors supply to CMS in their periodic disclosures of net acquisition costs would also be protected by the Trade Secrets Act (18 U.S.C. § 1905). We encourage CMS to include appropriate confidentiality provisions consistent with these statutory mandates in the final CAP rule.

E. Ensuring Public Input and Transparency

PhRMA appreciates CMS' efforts to work with CAP stakeholders in developing and implementing the program. Given the significant amount of regulatory work that remains before CAP is implemented in January 2006, and the important details concerning CAP implementation that might ultimately be developed through subregulatory guidance, we hope that CMS will continue to provide ongoing opportunities for stakeholder input regarding the program. In implementing the Part D benefit, for example, CMS has frequently released subregulatory guidance on various aspects of Part D implementation in draft form and invited public comments before finalizing the guidance. This approach has worked well in fostering a dialogue between

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[27] 70 Fed. Reg. at 10765.

[28] Id.

[29] SSA § 1847B(a)(1)(C), (c)(5) (emphasis added).

CMS and the program's stakeholders, and we would encourage CMS to adopt a similar collaborative approach as it moves forward with CAP implementation. Such an approach will provide CMS with ongoing access to the broad range of information it needs to structure the program successfully, and help to ensure the transparency needed to maximize physician and vendor participation. Similarly, issuing the CAP final rule as an interim final rule with comment period would provide the opportunity for stakeholder input that could help CMS quickly identify regulatory changes that would improve CAP's effectiveness.

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PhRMA hopes that these comments will be useful to CMS in crafting the CAP final rule and in implementing the program. We look forward to further dialogue on these issues and trust that CMS will not hesitate to contact us with any questions, comments, or requests for additional information.

Sincerely,

Richard I. Smith,
Senior Vice President for
Policy, Research, and Strategic Planning

Bruce N. Kuhlik
Senior Vice President and
General Counsel

Submitter : **Andrew Sperling** **Date: 04/26/2005**

Organization : **National Alliance for the Mentally Ill**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

Medicare Part B Competitive Acquisition Program, see attachment

CMS-1325-P-437-Attach-1.WPD

CMS-1325-P-437-Attach-2.DOC

NAMI
The Nation's Voice on Mental Illness

April 26, 2005

Dr. Mark McClellan
Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W. Room 445-G
Washington, D.C. 20201

Attention: CMS-1325-P; Part B Competitive Acquisition Program, Categories of Drugs to be Included under CAP

Dear Dr. McClellan:

On behalf of the 210,000 members and 1,200 affiliates of the National Alliance for the Mentally Ill (NAMI), I am pleased to submit the following comments on proposed regulations implementing the Medicare Part B Competitive Acquisition Program (CAP). As the nation's largest organization representing people with severe mental illnesses and their families, NAMI would like to urge the Centers for Medicare and Medicaid Services (CMS) to expand the CAP to include long-acting injectable medications to treat severe mental illness.

In NAMI's view, the CAP offers tremendous potential to benefit individuals with the most severe and disabling forms of mental illness for whom injectable medications can help maintain adherence to drug regimens, treatment that is life-saving and essential to successful recovery and a full life in the community. **NAMI would therefore urge CMS to:**

1. **include long-acting injectable antipsychotic medications in the initial phase of CAP implementation, and**
2. **not delay coverage of long-acting atypical anti-psychotics in the Part B CAP beyond the implementation date of Jan 1, 2006.**

Advantages of Injectable Psychiatric Medications

In 2003, the final report of President Bush's New Freedom Commission on Mental Health declared that recovery – helping individuals overcome the disabling aspects of mental illnesses – should be the overarching goal of our nation's public mental health system. Addressing the means for attaining this goal, the report stated, "To achieve the promise of community living for everyone, new service delivery patterns and incentives must ensure that every American has easy and continuous access to the most current treatments and best support services." In

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implementing the CAP program, NAMI believes that CMS has an opportunity to make a significant contribution to fulfilling the goals of the federal New Freedom Initiative by facilitating patient access to important psychiatric medications.

A growing body of evidence indicates that adherence to treatment with psychotropic medication regimens is similar to that for consumers who are prescribed medications for somatic illnesses. A review of the literature has found that most consumers probably only take 33 – 94 percent of their prescribed drugs, with the median being about 50 percent for long-term therapy, while a sizeable percentage are wholly non-compliant.[1]

At the same time, it should be recognized that for individuals living with schizophrenia, non-adherence to anti-psychotic maintenance treatment poses enormous risk of a terrifying downward spiral of psychiatric decompensation, psychotic relapse and rehospitalization. For consumers and families, non-adherence presents enormous clinical and economic challenges. Treatment failure triggered by non-adherence threatens an individual's psychiatric rehabilitation assignment and supported housing placement. Non-adherence also results in elevated risk for suicide.

Similarly, non-adherence results in significant costs across the treatment system more frequent use of outpatient resources off all kinds as well as significantly increased utilization of psychiatric emergency facilities. The consequences of non-adherence thus contributes substantially to schizophrenia's estimated annual cost of $33 billion to $65 billion. Therefore, the availability of new long acting psychotropic drugs through CAP should be examined from two perspectives: clinical outcomes and cost.

From a clinical standpoint, the use of long-acting injectable antipsychotics have been recognized as an important, evidenced-based practice that addresses the noncompliance issue for many people with schizophrenia and bipolar disorder. Moreover, the emerging new types of psychotropic drugs are showing tremendous promise in addressing the issue of *partial* adherence (less than 80% adherence) among persons with severe mental illness. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers and their family members found objectionable, including lingering pain after the injection, sedation and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

A number of the new injectable medications are currently in development (including an antidepressant). In addition, one of the newer atypical antipsychotic agents is already available in a long-acting injectable form and is showing great promise in treating schizophrenia. NAMI supports the development of these new technologies to expand access to injectable medications to help individuals with the most treatment resistant forms of illnesses such as schizophrenia and bipolar disorder.

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[1] Morris LS, Schulz RM. Patient compliance—an overview. J Clin Pharm Ther 1992, 17:283-95.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations are considered one of the most important practice guidelines ever developed for the treatment of schizophrenia. Among the important findings in the PORT were that the older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication..." The emerging evidence for the use of long-acting injection seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. Compliance is a significant issue in the treatment of schizophrenia, with 50 – 70 percent of all patients being only partially compliant in the first two years of treatment. A survey of studies found that non-adherence was associated with a risk of relapse that is 3.7 times greater than that for consumers who are able to adhere with prescribed treatment.[2]

Studies have found that use of a long-acting injectable is associated with fewer and shorter hospitalizations[3] and improved functioning and quality of life.[4] Given the promise of these new injectable medications to improve outcomes for patients and reduce healthcare costs, and the recognition of the use of injectable medications as an evidence-based practice, NAMI believes that CMS should make consumer access to injectable antipsychotic medications a priority. As other new injectable psychotropics become available, NAMI would recommend that CMS prioritize efforts to enhance consumer access to this promising therapy.

Cost considerations are deeply intertwined with the clinical issues noted above. A recent article in *Psychiatric Services* found that the risk of psychiatric hospitalization was closely correlated with treatment adherence. The presence of any gap in medication coverage was associated with an increased risk of hospitalization, *including gaps as small as one to ten days*; gaps of 11 to 30 days doubled the risk and gaps of more than 30 days almost tripled it [5]. As a result, consumers experiencing non-adherence have the lowest pharmacy costs, but the highest overall costs because of inpatient hospital utilization. Further, an April 2004 article in the *American Journal of Psychiatry* found that "excess prescription drug fillers" occupied in the next highest cost category – when compared with the non-adherent group[6]. In NAMI's view, long-acting injectable antipsychotics offer tremendous promise for eliminating these costs by dispensing with the prescription filling process altogether.

In short, studies have found that the use of long-acting injectable antipsychotics are associated with fewer and shorter hospitalizations and improved functioning and quality of life. Given the promise of these new injectable medications to improve clinical outcomes and reduce healthcare costs, and the recognition of the use of long-acting injectable medications as an evidenced-based practice, NAMI recommends that CMS make consumer access to injectable anti-psychotic medications an urgent priority. As other new injectable psychotropic drugs become available,

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[2] Fenton WS, Blyler CR, Heissen RK. Determinants of medication compliance in schizophrenia. Schizophr Bull. 1997, 637-651.

[3] Leal A, Rosillon D, Mehnert A et al. Healthcare resource utilization during 1-year treatment with long-acting injectable risperidone, Pharmacoepid Drug Safety, 2004, 13: 811-816.

[4] Nasrallah HA, Duchesne I, Mehnert A, et al. Health-related quality of life in patients with schizophrenia during treatment with long-acting injectable risperidone. J Clin Psychiatry 2004, 65:531-536.

[5] Weiden PJ, Grogg, A, et al. Partial compliance and risk of rehospitalization among California Medicaid patients with schizophrenia, *Psychiatric Services,* August 2004, 55:886-891.

[6] Am. J. Psychiatry, 2004, 161 692

NAMI would further suggest that CMS prioritize efforts to enhance consumer access to medications through CAP.

Current Obstacles Faced by Providers Using Injectable Psychiatric Medications
There is mounting evidence that community-based mental health providers -- including Community Mental Health Centers (CMHCs), public agencies and other multi-service community providers serving people with severe mental illnesses (especially those eligible for both Medicaid and Medicare) -- are facing significant obstacles in providing injectable medications to people who need them.

As safety-net providers, CMHCs and other public agencies are very often heavily burdened treatment settings that lack sophisticated information technology and a sufficient level of administrative staffing. For example, to provide access to sole long-acting injectable antipsychotic now on the market, CMHCs and psychiatrists at public sector agencies must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid.

Providers then bear the administrative burden of tracking the claims and the financial risk of receiving incomplete payment from one or both payers. This burden has become an enormous impediment to expanding access to this emerging technology to the full range of patients who could benefit from it. In some cases, CMHCs and other public agencies will only provide the medication to patients that are solely Medicaid beneficiaries. Including injectable antipsychotics in the Medicare CAP program would mark important progress in overcoming this substantial impediment, as providers would have the option to obtain the medications from a drug vendor that will handle reimbursement from Medicare. Helping providers expand access to this promising therapy will bring great benefit to people living with the most treatment resistant forms of schizophrenia.

In reviewing CMS's proposed rule for the CAP program, NAMI is concerned that it appears the agency views oncology medications as the primary medication category to be included in the initial phase of CAP. In NAMI's view CAP has tremendous potential to bring new psychiatric therapies into wider use and to significantly improve the quality of care for some of the most vulnerable people in our society. Inclusion of this promising treatment option in the CAP will also serve to further the goal of "achieving the promise" of President Bush's New Freedom Initiative for people living with severe mental illness.

NAMI therefore urges CMS to include coverage of antipsychotic injectable medications in the drug categories that compose the initial phase of the Medicare Part B CAP implementation. NAMI would also urge that CMS not delay coverage of long-acting atypical anti-psychotics under Part B beyond the implementation date of Jan 1, 2006.

Sincerely,

Michael J. Fitzpatrick, M.S.W.
Executive Director

Submitter : **Dr. Thomas Brown** **Date: 04/26/2005**

Organization : **Seven Counties Services and KPMA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

April 26, 2005
Center of Medicare and Medicaid Services
Room 445-D
Hubert H. Humphrey Building
200 Independence Ave., Southwest
Washington, DC 30201
Dear Sir or Madam:

I am writing in strong support of the proposed rule recently issued by CMS that addresses the competitive acquisitions program. This program has tremendous potential to benefit individuals with severe and persistent mental illnesses. I urge that injectable antipsychotic medications be included in the initial phase of CAP implementation.
Community Mental Health Centers (CMHC), which serve a large number of people with severs mental illnesses that are eligible for both Medicare and Medicaid, face serious financial and logistical obstacles in providing and accessing injectable medications. When injectable antipsychotic medications are included in the CAP program, providers and consumers will have easier access to appropriate and much needed medications.
As the largest CMHC in Kentucky, and one of largest in the country, Seven Counties Services has seen the benefits of long-acting antipsychotic medications in decreasing the use of higher cost inpatient care and improved compliance with outpatient services. Unfortunately, the current payment structure for these drugs has resulted in psychiatrists not being able to use these medications as effectively as possible. This situation recently resulted in a completed suicide because the patient was not being able to continue a very expensive long-acting injectable medication after his release from hospital.
I am also the President of Kentucky Psychiatric Medical Association (KPMA) and the other psychiatrists from the state of Kentucky both in private practice and CMHC physicians have experienced similar problems. The KPMA also recently voted to fully support the need for inclusion of injectable antipsychotic medication in the competitive acquisitions program to provide for the critical need for these medications for your patients health and the cost saving to the Medicare and Medicaid programs.

Sincerely,
Thomas Brown, MD
Vice-President of Medical Services, Seven Counties Services
Associate Clinical Professor, Department of Psychiatry, University of Louisville
President, Kentucky Psychiatric Medical Association

Submitter : **Mr. Thomas Leibfried** **Date: 04/26/2005**

Organization : **National Council for Community Behavioral Healthca**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1325-P-439-Attach-1.DOC

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National Council for Community Behavioral Healthcare

April 26, 2005

Dr. Mark B. McClellan
Administrator
Center for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Part B, Competitive Acquisition Program: 42 CFR 414/CMS-1325-P

Dear Dr. McClellan:

On behalf of the National Council for Community Behavioral Healthcare (NCCBH), I am writing to express our overall support for the proposed rule recently issued by the Centers for Medicare and Medicaid Services (CMS) to implement the Part B Competitive Acquisition Program (CAP). While this correspondence will address a number of regulatory issues growing out of the proposed rule, I want to emphasize that NCCBH's top priority is the inclusion of long-acting injectable atypical anti-psychotic medications in the final CAP rule.

I. Categories Of Drugs To Be Included Under CAP

A.) Regulatory Approach

The Medicare Prescription Drug, Improvement and Modernization Act (MMA) explicitly provides the Secretary with the discretion to select appropriate drug categories and appropriate geographic areas for the program. In turn, the proposed rule outlines four options for determining which medication classes should be included in the initial phase of CAP implementation.

In order to assure access under Part B to long acting injectable anti-psychotic medications, NCCBH strongly urges CMS to exercise the regulatory approach which would require all drugs furnished incident to a physician's service to be included in CAP. [pg, 24, CMS-1325-P]. As we discuss in greater later in this correspondence, community mental health centers (CMHCs) and other community-based mental health providers are experiencing increasing uncertainty – and the threat of un-reimbursed financial liabilities – as they attempt to obtain this emerging medical technology for their patients. By contrast, CAP offers both potential savings as well as a vastly simplified purchasing and delivery process. This is particularly attractive for public sector providers serving low-income individuals with severe and persistent mental disorders who typically operate with very constrained budgets and limited administrative personnel.

In our view, it is also important for CMS to be cognizant of the ever-changing medical landscape, which is marked by clinical breakthroughs and emerging technologies. Oncology medications are incredibly significant to the health and well being of people living with cancer. The proposed rule is replete with references to chemotherapy drugs, in part, because they currently compose 80% of all Part B medication expenditures. On rare occasions, CMS-1325-P also discusses medicines typically prescribed in other medical specialty areas: hematology, internal medicine, infectious disease, urology, rhemautology, and obstetrics/gynecology.

However, long-acting injectable atypical anti-psychotic medications only cleared Phase III clinical trials and won Food and Drug Administration (FDA) approval after MMA was passed. As we understand it, several more products are in various stages of the FDA drug approval process. For reasons that are described immediately below, the addition of these drugs to the medication armamentarium of psychiatrists working in CMHCs could substantially improve clinical outcomes for low-income persons living with schizophrenia and bipolar disorder. The National Council believes that injectable anti-psychotics should not excluded from CAP simply as a result of late market entry, and the decision about which drugs to include should not solely be based upon past prescribing practices under Part B. The tests for inclusion under CAP should be drug safety and efficacy, and optimizing clinical outcomes for patients who could benefit from new medical technologies.

B.) Injectable Psychiatric Medications: Improved Clinical Outcomes

Compliance with treatment, or treatment adherence, is a very key clinical consideration. In prescribing medication, compliance usually means "the extent to which the patient takes the medication prescribed" (Fawcett, 1995). Many mental disorders require more than just a brief medication intervention. For people with severe and persistent mental illnesses like schizophrenia and bipolar disorder, years of medication therapy or even lifelong medication intervention is necessary.

Modern treatment for these devastating mental conditions typically involves the use of atypical anti-psychotic medicines. In fact, Dilip Jeste, M.D. a professor of psychiatry and neurosciences and the Estelle and Edgar Levi Chair in Aging at the University of California at San Diego School of Medicine, recently said: "Antipsychotic medications are the cornerstone of therapy." Yet, reported rates of nonadherence (noncompliance) to antipsychotic range from 20% to 89%, with an average rate of approximately 50%; a significant percentage are wholly noncompliant. In patients with schizophrenia, nonadherence to anti-psychotic maintenance treatment leads to a terrifying downward spiral of psychiatric decompensation, psychotic relapse and rehospitalization.

For community mental health centers (CMHCs), these cases present enormous clinical and economic challenges. Treatment failure triggered by noncompliance threatens a patient's psychiatric rehabilitation assignment and supported housing placement; during decompensation, the suicide risk averages 10%.[1] Similarly, noncompliant individuals represent the highest cost cases. Among other things, nonadherence results in more frequent use of outpatient resources of all kinds as well as significantly increased utilization of psychiatric emergency facilities. The

[1] *Mental Health: A Report of the Surgeon General,* U.S. Department of Health and Human Services, Pg. 269, 1999.

consequences of noncompliance thus contribute substantially to schizophrenia's estimated annual cost of $33 billion to $65 billion. Therefore, the availability of new long acting psychotropic drugs through CAP should be examined from two perspectives: clinical outcomes and cost.

From a clinical standpoint, the use of injectable antipsychotics have been recognized as an important, evidenced-based practice that addresses the noncompliance issue for many people with schizophrenia and bipolar disorder. The new type of psychotropic drugs discussed herein also show tremendous promise in addressing the issue of *partial* compliance (less than 80% adherence) among persons with mental illnesses. These new medications are injectable, but do not have the side effect profile of older injectable depot psychotropics that consumers found objectionable, including lingering pain after the injection, sedation and other effects. While a number of the new injectable medications are currently in development (including an antidepressant), one antipsychotic, an injectable form of risperidone, has been employed successfully in community-based settings for about a year, and it has shown great promise in treating schizophrenia.

The Schizophrenia Patient Outcomes Research Team (PORT) treatment recommendations, considered one of the most important practice guidelines for the treatment of schizophrenia, find that older injectables are an important therapy for schizophrenia, stating that depot injectables should be "strongly considered for persons who have difficulty complying with oral medication....." The emerging evidence for the use of risperidone long-acting injections seems to indicate that the new injectable antipsychotics may offer significant clinical advantages to the older depot injectables, in addition to addressing the issue of noncompliance. As stated earlier, compliance is a significant issue in the treatment of schizophrenia, with 50% to 70% of all patients being only partially compliant in the first two years of treatment. A survey of studies found that noncompliance was associated with a risk of relapse that is 3.7 times greater than that for compliant patients.[2]

Not surprisingly, cost considerations are deeply intertwined with the clinical issues described immediately above. Specifically, a recent article in *Psychiatric Services* found that the risk of psychiatric hospitalization was closely correlated with compliance. The presence of any gap in medication coverage was associated with an increased risk of hospitalization, **including gaps as small as one to ten days;** gaps of 11 to 30 days doubled the risk and gaps of more than 30 days almost tripled it.[3] As a result, nonadherent patients have the lowest pharmacy costs, but the highest overall costs because of inpatient hospital utilization. Interestingly, an April 2004 article in the *American Journal of Psychiatry* found that "excess prescription drug fillers" occupied in the next highest cost category – when compared with the nonadherent group.[4] Needless to say, injectable antipsychotics would eliminate these costs by dispensing with the prescription filling process altogether.

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[2] Fenton WS, Blyler CR, Heissen RK. Determinants of medication compliance in schizophrenia. Schizophrenia Bulletin 1997, 637-651.

[3] Weiden PJ, Grogg, A, et al. Partial compliance and risk of rehospitalization among California Medicaid patients with schizophrenia, *Psychiatric Services,* August 2004, 55:886-891

[4] Am. J. Psychiatry, 2004, 161 692

In sum, studies have found that the use of long-acting injectable risperidone is associated with fewer and shorter hospitalizations and improved functioning and quality of life. Given the promise of these new injectable medications to improve clinical outcomes and reduce healthcare costs, and the recognition of the use of injectable depot medications as an evidenced-based practice, we believe that CMS should make consumer access to injectable anti-psychotic medications an urgent priority. As other new injectable psychotropic drugs become available, we suggest that the agency prioritize efforts to enhance consumer access to medications through CAP.

C.) Current Obstacles Faced by CMHCs Using Injectable Psychiatric Medications

Aside from the clinical considerations, the confusion inherent in the existing dual track "buy and bill" system is reducing access to this important new medical technology. CMHCs and other multi-service commuity providers, which serve 4.5 million American with mental illnesses, face serious obstacles providing injectable medications under current purchasing rules. As safety-net providers, CMHCs are very often heavily burdened treatment settings that lack sophisticated information technology and sufficient levels of administrative staffing. Nonetheless, to furnish the new injectable antipsychotic risperidone to patients, CMHCs must first purchase the medication, and then seek reimbursement from both Medicare (which makes only partial payment for mental health drugs) and Medicaid. Providers then bear the administrative burden of tracking the claims as well as the financial risk of receiving incomplete payment from one or both payers. This burden has become an impediment to expanding access to this medication to the full range of patients who could benefit from it.

In some cases, CMHCs will only provide the medication to patients that are solely Medicaid eligible. When injectable antipsychotics are included in the Medicare CAP program, this substantial impediment will be removed, as providers would have the option to obtain medications from a regional drug vendor that will handle reimbursement from Medicare. **Indeed, CAP seems to be precisely tailored for CMHCs because they "do not want to be in the drug procurement.....business and....would prefer to obtain drugs....under CAP," in the words of the proposed rule.**

In closing, CAP has the potential to bring new psychiatric therapies into wider use and significantly improve the quality of care for some the most vulnerable people in our society – helping to "achieve the promise" of President George W. Bush's New Freedom Initiative for people with psychiatric disabilities. We urge you to include coverage for antipsychotic injectable medications in the drug categories that compose the initial phase of CAP implementation.

Thank for your consideration of this very important matter.

Sincerely,

Linda Rosenberg

Linda Rosenberg
President & CEO

Submitter : **Mr. Alan Chaveleh** **Date: 04/26/2005**

Organization : **Healix Infusion Therapy, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

1-15

Categories of Drugs to be Included under the CAP

CMS is soliciting commentary on ways in which to define and implement the drug categories. We believe the best way to categorize drugs is by individual specialty. Such a division of drug categories would allow the vendor to provide appropriate clinical support for the drug category and allow CMS to address the individual quality of service needs of a category. For example, some specialties may require that the drugs be delivered within a day; whereas, another specialty will have a requirement for refrigeration or packaging.

Competitive Acquisitions Areas

CMS has proposed three options for Competitive Acquisition Areas: national, regional and state-by-state. A national competitive acquisition area may limit the number of available vendors who can compete in the CAP program. Based upon our drug purchasing experience, regional wholesale companies can be more competitive on price and service than national vendors.

In discussing regional areas, CMS has looked at defining the acquisition area based on existing markets for regional distributors and specialty pharmacies. Such a move would tend to favor the few distributors and specialty pharmacies known to CMS. We would caution CMS to be thorough in its examination of the division of regions so as not to favor one vendor over others.

We would also note that the proposal for just four regions will limit the ability of smaller regional vendors to compete and may artificially raise bid prices by forcing such vendors to build new distribution facilities to service CMS in these super-regions.

Claims Processing Overview

The requirement that the physicians actually administer the drugs to a patient before payment to the vendor has the implicit requirement that the physician must comply with Medicare or Medicaid?s guidelines on such course of treatment or there will be no payment for the drugs or administration. For example, when the physician has not shown medical necessity, payment will not be made for either the physician services or the drugs. Under the ASP model, the clinician making the determination as to whether or not to provide treatment bears the financial burden of the drugs if that physician fails any of the elements necessary for Medicare or Medicaid to pay for that course of treatment. Under the CAP model, the physician has no financial liability for often-times very expensive drugs. Thus, the physicians are not penalized for carelessness in documentation or carelessness in complying with a local carrier?s guidelines for administering the drug.

The statutory requirement that Medicare and Medicaid do not pay for drugs unless they are administered leaves vendors without recourse once physicians receive a drug. We recommend that CMS pay vendors once the physician orders the drugs and they are delivered to the physician. In the alternative, we suggest that CMS devise a mechanism for Medicare and Medicaid to reimburse the vendor for drugs administered, even if the local carrier denies coverage for that administration. Where drugs are ordered or used, the vendor should not have to write off the cost of the drugs because of issues not within the control of the vendor, such as, a patient failing to come to the physician to get the drugs administered, or the physician omitting the prescription number on their HCFA form.

Bidding Entity Qualifications

CMS has proposed a number of financial and management criteria for the vendor. One aspect CMS has not yet discussed is the vendor?s ability to assist the physician participants or the beneficiaries of clinical problems. We believe it is important that the vendors have demonstrated clinical capabilities to service the physicians and their patients. Many of the drugs that will fall under the CAPS program are high-dollar, complex drug therapies that will require clinical support. Clinical services are alluded to in the Proposed rule and can add value to physicians and patients.

GENERAL

GENERAL

(See attachment)

CMS-1325-P-440-Attach-1.DOC

25 April 2005

Department of Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1325-P
Electronically Delivered

Comments on Competitive Acquisition of Outpatient Drugs & Biologicals ("CAP")

These comments are submitted by Healix Infusion Therapy, Inc., an infusion therapy management and drug supply company. Healix has experience in helping specialties such as oncology, neurology, infectious diseases, and rheumatology manage the provision of complex drug therapies to patients. In that capacity, we have the unique perspective of three major stakeholders in the proposed CAP—the vendor, physician and patient. Healix has number of concerns about the CAP.

Competitive Acquisition Areas

CMS has proposed three options for Competitive Acquisition Areas: national, regional and state-by-state. A national competitive acquisition area may limit the number of available vendors who can compete in the CAP program. Based upon our drug purchasing experience, regional wholesale companies can be more competitive on price and service than national vendors.

In discussing regional areas, CMS has looked at defining the acquisition area based on existing markets for regional distributors and specialty pharmacies. Such a move would tend to favor the few distributors and specialty pharmacies known to CMS. We would caution CMS to be thorough in its examination of the division of regions so as not to favor one vendor over others.

We would also note that the proposal for just four regions will limit the ability of smaller regional vendors to compete and may artificially raise bid prices by forcing such vendors to build new distribution facilities to service CMS in these super-regions.

Competitively Biddable Drugs

CMS is soliciting commentary on ways in which to define and implement the drug categories. We believe the best way to categorize drugs is by individual specialty.

14140 SW Freeway, Floor 4 • Sugar Land, TX 77478 • t: 281.295.4000 t: 1.800.422.2204 f: 281.295.4052
www.healix.cc

Such a division of drug categories would allow the vendor to provide appropriate clinical support for the drug category and allow CMS to address the individual quality of service needs of a category. For example, some specialties may require that the drugs be delivered within a day; whereas, another specialty will have a requirement for refrigeration or packaging.

Claims Processing Overview

The requirement that the physicians actually administer the drugs to a patient before payment to the vendor has the implicit requirement that the physician must comply with Medicare or Medicaid's guidelines on such course of treatment or there will be no payment for the drugs or administration. For example, when the physician has not shown medical necessity, payment will not be made for either the physician services or the drugs. Under the ASP model, the clinician making the determination as to whether or not to provide treatment bears the financial burden of the drugs if that physician fails any of the elements necessary for Medicare or Medicaid to pay for that course of treatment. Under the CAP model, the physician has no financial liability for often-times very expensive drugs. Thus, the physicians are not penalized for carelessness in documentation or carelessness in complying with a local carrier's guidelines for administering the drug.

The statutory requirement that Medicare and Medicaid do not pay for drugs unless they are administered leaves vendors without recourse once physicians receive a drug. We recommend that CMS pay vendors once the physician orders the drugs and they are delivered to the physician. In the alternative, we suggest that CMS devise a mechanism for Medicare and Medicaid to reimburse the vendor for drugs administered, even if the local carrier denies coverage for that administration. Where drugs are ordered or used, the vendor should not have to write off the cost of the drugs because of issues not within the control of the vendor, such as, a patient failing to come to the physician to get the drugs administered, or the physician omitting the prescription number on their HCFA form.

Bidding Entity Qualifications

CMS has proposed a number of financial and management criteria for the vendor. One aspect CMS has not yet discussed is the vendor's ability to assist the physician participants or the beneficiaries of clinical problems. We believe it is important that the vendors have demonstrated clinical capabilities to service the physicians and their patients. Many of the drugs that will fall under the CAPS program are high-dollar, complex drug therapies that will require clinical support. Clinical services are alluded to in the Proposed rule and can add value to physicians and patients.

Physician Election Process

CMS proposes to require that physicians participate in the CAP program for an entire year. This requirement will have the potential of reducing the quality of care for patients because the physicians may find that the CAP program delays the availability of drugs and yet, the physician will have no mechanism to terminate the CAP arrangement and go back to the ASP model. For example, an infectious disease physician may find it more difficult to administer intravenous antibiotics immediately because the vendor's quickest delivery for such drugs is one day. Although use of the physician's inventory is possible, the reporting requirements and the administrative burden associated with that use may reduce a physician's willingness to immediately administer such drugs. Thus, we suggest that physicians have the ability to opt out of the CAP program at any time.

Conclusion

We believe that CAP has the potential to assist physicians with medication access problems. However, the statutory requirements in the CAP Model places undue financial risk on CAP vendors for activities outside their control and would prevent any potential vendor from participating. If these statutory constraints are corrected and specialty specific regional vendors are established, CAP can have positive impact on in-office physician services.

Please feel free to call me at the number listed below if you have any questions or comments.

Sincerely,

/Alan B. Chaveleh/

Alan B. Chaveleh
President

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Submitter : **Ms. Derek Robertson** **Date: 04/26/2005**

Organization : **The Hemophilia Alliance, Inc.**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-1325-P-441-Attach-1.DOC

The Hemophilia Alliance, Inc.

April 26, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

RE: CMS 1325-P: Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

Dear Dr. McClellan:

I am writing in response to the proposed rule for the competitive acquisition of outpatient drugs and biologicals under Medicare Part B.[1] The Hemophilia Alliance, Inc. (the "Alliance") currently represents thirty-eight Hemophilia Treatment Centers (HTCs) that buy and sell blood clotting factors to their patients under the Public Health Service (PHS) Section 340B discount drug pricing program. These HTCs distribute factor to Medicare beneficiaries and receive reimbursement under Medicare Part B.

We commend the Centers for Medicare and Medicaid Services (CMS) for the extensive proposals for implementation of the Competitive Acquisition Program (CAP) and appreciate the opportunity to comment.

Comments on Proposed Rule

(i) Categories of Drugs to be Included under the CAP

The Alliance supports the interpretation of the law provided by CMS in the proposed rule. We agree with the CMS statement that, "...we do not believe it is possible to include drugs other than those administered as incident to a physician's service as part of this program".[2] In the vast majority of cases, clotting factors, which are used by persons with bleeding disorders either to treat bleeds or prophylactically to prevent bleeds, are obtained directly from HTCs or specialty pharmacies and not from physicians. These providers are equipped to offer a range of necessary services, including specialized storage, assay management, shipment, and ancillary supplies. The drugs and supplies are then maintained and self-administered in the home setting.

[1] 70 Fed. Reg. 42, 10746 (2005) (to be codified at 42 C.F.R. pt. 414) (proposed March 4, 2005).
[2] *Id.* at 10749.

1875 Eye Street, NW • Washington, D.C. 20006 • Phone: 202.872.6764• derek.robertson@ppsv.com

The nature of the drugs themselves, the way they are obtained, and the method by which they are administered make them ill suited for the competitive bidding model.

Given that the purchase and distribution of clotting factor are not pursuant to a physician's service, these drugs should not fall within the scope of the CAP. In addition, the perceived benefits of the CAP; reducing a physician's financial burden and eliminating the need for physicians to collect coinsurance[3] would not be applicable in the case of these drugs.

The Alliance requests that CMS explicitly exclude clotting factor products from competitive acquisition in the final program rule.

(ii) Competitive Acquisition Areas

Even if one could argue that drugs not incident to a physician service should be included in the CAP, other aspects of this program would be problematic for clotting factor.

The proposed Competitive Acquisition Areas (CAAs), whether, national, regional or statewide would be disruptive to the current distribution system for clotting factor. Currently, there are several distributors of factor whose reach depends on their size with larger providers having a national presence and HTCs in the Alliance limited, by law, to only serve their own patients locally. By establishing CAAs, the selected vendor would, in fact, eliminate smaller providers from the market thereby reducing competition and choice for Medicare beneficiaries. This reduction in providers would be forced and not voluntary as envisioned by the concept of the CAP, with some physicians who don't want to be in the business of selling drugs opting to purchase from the selected vendor.

Summary

The CAP, when implemented, may provide tremendous benefit to some physicians. However, as stated by CMS, this program is designed for drugs which are dispensed incident to a physician's service and for physicians who do not want to be in the business of purchasing drugs. Clotting factor is not dispensed incident to a physician service and physicians do not purchase or sell these drugs. For both these reasons, clotting factor should be explicitly excluded from the CAP.

The current system of distribution by HTCs and specialty pharmacies works well for providers and Medicare beneficiaries. Explicitly excluding clotting factor from the CAP in

[3] *Id.* at 10748.

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the final rule will ensure that these beneficiaries continue to get their medication in a manner that best suits them.

The Alliance appreciates your attention to this matter of importance to persons with hemophilia and other bleeding disorders who are dependent upon these life-sustaining products. Please contact me at 202-872-6764 if you have any questions regarding these comments or hemophilia management in general.

Sincerely,

Derek Robertson
General Counsel

1875 Eye Street, NW ▪ Washington, D.C. 20006 ▪ Phone: 202.872.6764▪ derek.robertson@ppsv.com

Submitter : **Ms. Pamela Conyers** **Date: 04/26/2005**

Organization : **RBHA**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

As a nurse, I have the worked with many patients or consumers who have medicare coverage for hospitalization. So, I was very please to learn about CAP. Many medicare beneficaries are compliant with doctors appointments however, lack the resources and funds for medications that are necessary to maintain proper physcial and mental health. It is important that CMS include psychiatric drugs and long-acting injectables in the initial stages of CAP. Consumers on long-acting injectables have a decrease in hospitalizations and once stablized are able to live productively in the community. When psychiatric drugs easier to access, we should see an overall improvement in mental health as well as physical health. This is truly healthcare reform.

Submitter : Dr. Anthony Siegel **Date:** 04/26/2005

Organization : Consilium Healthcare International

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

Note: CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

Submitter : **Mrs. Lynn Kuhn** **Date: 04/26/2005**

Organization : **South Texas Oncology and Hematology, P.A.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

I am writing today as a concerned citizen of the United States, an Administrator of an Oncology Clinic, a friend of multiple cancer survivors anda relative of a grandmother and aunt who succumed to this dreadful disease.

Over the past 12 years I have seen what a wonderful mechanism we have for delivering cancer care to millions of very ill people accross the country. It is devastating to me to watch as this great machine is rapidly being dismantled because of what appears to be a lack of understanding of how the system works. Ther current drug delivery system developed by community cancer care is a time-tested, proven system. It is extremely effective and efficient in providing treatment to Americans battling cancer. To substitute this proven delivery system with a concept that has not been tested is very dangerous.

Attached are just a few specific problems that are foreseen with the Competitive Aquisition Program (CAP). There are numerous other issues that will inevitably occur as the program is rolled out.

CMS-1325-P-444-Attach-1.DOC

Problem #1: You are locked into a CAP vendor for one year
An oncologist who elects to participate in CAP will be "locked-in" for one year. The oncologist will not be able to leave CAP unless the approved vendor ceases to participate in the program, the oncologist relocates to another area that is not served by the CAP vendor, or other criteria is met as established by the Secretary of Health and Human Services.
Problem #2: CAP vendors can establish formularies
CAP vendors will have authority to establish formularies and these formularies will be driven by price, not clinical effectiveness. Participating oncologists have a choice: accept the CAP supplied drug (which may not be the most effective or appropriate) or purchase drugs outside CAP under the Medicare ASP-based reimbursement system.
Problem #3: Individual patient inventories
CAP vendors are prohibited from delivering drugs and biologicals to a participating oncologist except upon receipt of a written prescription. This means that orders placed and filled under CAP are specific to a particular patient and the CAP participating oncologist must maintain an electronic or paper, patient-specific inventory for each patient. Individual inventories also create potential for millions of dollars of "waste" from unused and unusable medications.
Problem #4: Patient inconvenience and inventory resupply
Under CMS' proposed rules, CAP participating oncologists are prohibited from using CAPacquired
drugs and biologicals to resupply their inventories unless all four of the following conditions are met: (1) the drugs are required immediately; (2) the oncologist could not have anticipated the need for the drugs; (3) the vendor could not have delivered the drugs in a timely manner; and (4) the drugs were administered in an emergency situation. In situations where a scheduled treatment for a patient does not happen as planned because the patient's needs have changed, the patient's appointment will have to be rescheduled pending shipment and delivery of a new CAP "order."
Problem #5: No emergency provisions
No provision is made for emergency delivery of drugs. Under proposed rules, CAP vendors only would be required to furnish routine shipments of drugs within one or two business days and to furnish emergency drug orders on the next day for orders received by the vendor before 3 p.m.
Problem #6: Burdensome claims processing
A primary goal of CAP is to give oncologists an alternative way to acquire drugs without the cost and burden of purchasing them and seeking reimbursement through the Medicare claims process. Yet, to participate in CAP, an oncologist must sign an election form that commits the oncologist to order drugs via a written prescription for each individual patient; submit Medicare claims within 14 days of the date of drug administration that includes the name and HCPCS code of the drug administered, the prescription number for each drug administered, and the date of service; provide information to the vendor regarding patients to help the vendor collect applicable deductibles and coinsurance; notify the vendor when a drug is not administered; and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP oncologist's drug administration claim is denied. Oncologists receive no payment or compensation for any of these services.
Problem #7: Vendors may have oncologists investigated and excluded
While no provision is made to compensate oncologists for administrative tasks associated with CAP, if a vendor experiences losses because an oncologist has failed to timely file claims or pursue appeals, the vendor may appeal to the designated carrier and request that the oncologist be investigated. The investigation may lead to exclusion, a notice of which is published in the Federal Register.
Problem #8: Treatment splitting
If an oncologist places an order for a patient's entire course of treatment at one time, the CAP

vendor is permitted to split the order into different shipments without the oncologist's authorization. When an order is split, the CAP vendor must create a separate prescription number for each shipment and the oncologist must track each shipment separately.

Problem #9: Quality control and lack of vendor responsibility

If a CAP participating oncologist has concerns about a vendor's performance, the proposed rule states that oncologist's recourse is to file a grievance with the vendor. If the grievance isn't resolved, the oncologist can escalate the matter to the designated carrier. Concerns about quality and service, however, are not grounds for terminating the oncologist's election to acquire drugs from the vendor — the oncologist is still locked-in to the one-year CAP election.

Problem #10: Pharmacy costs are un-reimbursed

Althougn a primary goal of CAP is to reduce the financial burden of drug acquisition on community cancer clinics, clinics will still incur costs associated with drug handling and inventory management. Add these to the additional "uncompensated" costs of ordering, tracking, and filing CAP claims, pursing appeals and sharing information with vendors to help them collect co-payments and it is clear that community cancer clinics, who are already facing a reimbursement shortfall, will experience further reimbursement erosion as a result of CAP.

Thank you for your time and attention to this matter.

Submitter : **Mrs. nora lott haynes** **Date: 04/26/2005**

Organization : **NAMI**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Please include mental health injectable drugs in this program.

Medicad and medicare rec'p are being denied assess because providers don't know how to bill. Please make it a part of the initial program to begin in 2006

Submitter : **Ms. Patricia Strode** **Date: 04/26/2005**

Organization : **NAMI Georgia**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

NAMI GEORGIA
3050 Presidential Dr., Ste. 202, Atlanta, GA 30340, 770-234-0855

April 13, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1325-P
P. O. Box 8010
Baltimore, MD 21344-8010

Dear Sir/Madame,

I am writing to express my concern regarding the Medicare Competitive Acquisition Program (CAP), for Part B drugs, specifically the long acting injectable anti-psychotic medications. As a mental health advocate, a parent of an adult child with mental illness, and the Executive Director of the National Alliance for the Mentally Ill of Georgia (NAMI Georgia), I am appealing to you to include psychiatric medications in the CAP program.

For various reasons, millions of Americans now receive long acting injectables, as a part of their treatment regimen. Many of them, because of those medications, are now able to maintain varying degrees of recovery including stable employment, reunification with families, independent living, and continuing education. Changes limiting access to injectables would reverse, in some cases, diminish in others, the progress made in recovery.

On behalf of NAMI Georgia, I advocate strongly for the inclusion of mental health therapies in Phase I of the Competitive Acquisition Program. In addition, we ask that serious consideration be given to the use of specialty pharmacy providers for the dispensing of these crucial therapies.

The National Alliance for the Mentally Ill of Georgia is a self-help, grassroots, advocacy organization. Made up of mental health consumers, their families, friends and mental health professionals, NAMI?s mission is to improve the lives of persons affected with mental illness. NAMI Georgia, an affiliate of the national organization, represents and serves Georgians affected by mental illness.

We thank you for your consideration in this matter, and for your attention to this correspondence.

Respectfully,

Patricia Strode
Executive Director

Submitter : **Ms. Lisa Getson** **Date: 04/26/2005**

Organization : **Apria Healthcare**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS:
Attached please find Apria Healthcare's official comments on CMS 1325-P regarding the proposed competitive acquisition program for drugs. Lisa Getson, Apria Healthcare

Submitter : Dr. Theo Manschreck **Date:** 04/27/2005

Organization : Harvard Medical School

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment. April 26, 2005

CMS-1325-P-448-Attach-1.DOC

To: Centers for Medicare and Medicaid Services
DHHS
Attn: CMS-1325-P

From: Theo C. Manschreck MD MPH, Professor of Psychiatry, Harvard Medical School, Medical Director, Corrigan Mental Health Center, Fall River MA 02720

RE: CAP Proposed Rule Comments

Date: April 26, 2005

This letter expresses my hopes for change through the Competitive Acquisition Program as its final rules are determined.

Specifically, as a psychiatrist and medical director of a public sector mental health center, I am deeply aware of multiple access problems concerning pharmaceutical products for mental disorders.

It is crucial that CMS include psychiatric medications in the initial stages of CAP (Phase I) to reduce barriers to access in the current system.

It is also crucial for CMS to define a category of Part B drugs that includes psychiatric medications, including long acting injectable antipsychotic products.

In summary, limited accessibility for mental disorder treatments continues to be a major need in public health terms for mentally ill individuals in the US population. All decisions in the CAP proposal that work in the direction of ease and access are essentially to be commended.

Submitter : Mr. Mickey Johnson **Date:** 04/27/2005

Organization : NAMI

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please include mental health injectables. Mental health consumers are being denied medication because saupplliers do not know how to bill.

Submitter : **Dr. David Kauder** **Date: 04/27/2005**

Organization : **AUA**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I think that the new proposed addition to the CMS physician administered medication (the CAP Program) will not be a good thing for the patients, the doctors or the health system. We are at present going through a monumental change in the delivery of these types of medications. The new rules have just gone into effect January 1. This was a quantum change in the delivery of these medications. We do not as yet know the costs, or effectiveness to the system. Now to introduce an even more radical change that is once again untested is unwise. The system, as presented, will add to the physicians "paperwork" burdens just by virtue of the restricitons on the use of these medications. The physician will locked into an untested system that has the potential for patient discomfort, the patient being forced to take a new and different medication at a very vulnerable time in their life.
This is untested and unwise and should be scrapped in its present form.
David H. Kauder, MD, FACS

Submitter : **Ms. Juanita Burnett** **Date: 04/27/2005**

Organization : **Ms. Juanita Burnett**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Purpose is to express my support for the Competitive Acquisition of Outpatient Drugs. Specifically, I request that behavioral heatlth drugs be included under this new program in January 2006.

Submitter : Mr. eric laskowich **Date:** 04/26/2005

Organization : TLC Cancer Clinic Surinder Vohra MD

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The CAP program as proposed by MMA would be a disaster. It seems to be a system out of sync with the realities of cancer care.
1. drug therapies are changed 25% of the time on the day of chemo. Vendor and Medicare need to be informed of this happening. This is work to us.
2. Debt is floated for patients due to the patients financial needs in a Dr office. Will a vendor do that. Will the bill by the vendor give my patients a heart attack while they are trying to beat their cancer.
3. We have to bill Medicare within 2 weeks. We are a small office with only one person who knows billing. How do we give him a vacation or if he gets sick?
4 Normal stuff I look for in a vendor is. service, proper delivery of a product, my employee and patients safety (refrigerated products in cold storage, chemo in plastic bags since several drugs can irritate skin and are poisonous if there is breakage, delivery in a timely manner).Does CMS guarantee that?
5 the drug delivery system is not broken. You are not accomplishing anything here or very little. WHY??
6 You have erred or revised many of the MMA laws.
G codes have been revised 3 or 4 times since January 2005. The rules have been given to us so late in the year the local carriers have made many mistakes. For rules to be implemented January 1st 2004 you gave us the rules December 30th 2003. The rules for 2005 were given to us Dec 10th 2004. This creates an appeals nightmare with the local carriers. HGSA will only take 10 appeals at a time(and I have dozens of appeals) and it takes over 30 minutes to get telephone appeals on the phone. Why should oncologists believe CAP won't be riddled with revisions and errors also. And there is no grace period. If you screw up we can we opt out of CAP? Who is going to join CAP for 2006. So far not me!
6 I even have more objections but these will do for now. The implementation of MMA has been a sloppy mess and you have done a disservice to the offices of the Community Oncologists.

Submitter : **Mr. Mal Hollander** **Date: 04/26/2005**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

As an administrator of a community based oncology practice I wish to give comments on the proposed CAP program.

Drugs: The practice of oncology is very variable and time critical based on the patient.s moment to moment condition. We do not know what the patient will actually be given on any treatment day until the patient is assessed and a current set of labs presented to the physician. We have to keep a range of drugs in stock to accommodate this and do not pre mix the drugs so there will not be unnecessary waste. This extra waste will add to the cost of the CAP program as the drugs will be shipped patient specific and we will not be able to use them for another patient.

The program requires a major increase in our overall practice expense from both a staffing and space utilization standpoint. We will have to have a separate ordering procedure, receiving and stocking of the drugs. There will need to be administrative oversight including compliance.

The risk to the practice will be great since we will be responsible for spoilage (refrigerator failure) or breakage. Business 101 in the US teaches that businesses to survive must offset risks with appropriate revenues (margin).

If the full range of drugs are not available from the CAP vendor then we will have a dual system operating which will complicate the complete patient care, billing and compliance issue.

The billing of the payments to the patients by the CAP vendor will cause havoc in our office since most of the patients will contact our billing staff to clarify or discuss the issue. This will again increase our operating costs and negatively impact patient care.

There is no guarantee that the CAP vendor will continue to ship the drugs for the patient that is not paying their bill. This will interfere in the care of the patient and leave our physicians at risk for malpractice if treatment is disrupted by the CAP vendor.

The billing issue of timely filing within the 14 days of administration of the drug is a major change in the time to file a claim in Medicare as well as private payers.

If a CAP vendor is unresponsive to our needs, we will have no choice but to continue to use them for a year if we elect to use the CAP program. We deliberately do not entertain this type of arrangement with our vendors to have the option of dealing where we feel secure.

The system does not have any safety nets for the problems that we are currently addressing in the ASP +6% system including manufacturer.s price increases that are not represented in our current payments and a myriad of other problems. The MVI vendors will be at high risk.

Financially they do not have the medical relationship that we have with the patients and probably will use hard collection tactics that might make the patient shy away from appropriate care.

Based on the problematic implementation of the 2005 ASP +6% & G codes it is highly advised to go very cautiously into these untried waters. The results of a break down of the delivery system will impart high risks to the health of the patients and the increased costs from alternate delivery methodology and decreased outcomes for the money spent.

Respectfully submitted
Mal Hollander

Submitter : **Dr. Kevin Mulvey** **Date: 04/26/2005**

Organization : **Hematology & Oncology Associates of Eastern Idaho, PLLC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

CMS-1325-P
Attached are my comments regarding the proposed regulations for the Competitive Acquisition Program.

We do not intend to use the Competitive Acquistion Program in our practice.

CMS-1325-P-E7-Attach-1.doc

Centers for Medicare and Medicaid Services
Comments on Competitive Acquisition Program
CMS-1325-P

Mark B. McClellan, MD
Administrator

In response to the Proposed Rule published in the March 4, 2005 Federal Register regarding the creation of the Competitive Acquisition Program (CAP) as a mechanism for providing Part B drugs to physician offices.

"Categories of Drugs to be included under the CAP". Allowing Vendors to Limit Availability of Drugs within Categories. While vendors will be required to bid on all HCPCS codes within a category, (e.g. drugs used by oncologists), CMS is proposing that vendors not be required to provide every National Drug Code associated with a HCPCS code. In effect, this give a vendor permission to establish a formulary by choosing which drugs it will make available through CAP.

Comment: Cancer treatment is complex and poses many risks to patients. Although oncology drugs may be in the same class and category, they are not fungible. Active ingredients, for example, may be similar, but inactive ingredients may act quite differently when combined with other drugs in a complex, multi-treatment regimen. Certain drugs may be less effective or more costly to administer (e.g., the drug takes extra time to reconstitute, or fails to mix properly – leaving particulate matter and needed treatment at the bottom of the bag instead of in the patient). Furthermore, different drugs within the same class or category can have different FDA approvals and different indications for use. A prime example is Procrit® and Aranesp. For certain types of treatments, some may consider these drugs to be interchangeable; however, the drugs are different because each drug has a different indication for use. Similarly, interferon drugs, while in the same category, also have different indications and FDA approvals.

Recommendation: The final rule must make clear that formularies are not permitted. Further, the final rule should provide that during the annual election period and upon request thereafter, a CAP vendor must fully disclose each drug that the vendor will make available pursuant to its CAP contract. In addition, vendors must be prohibited from making any changes in the list of drugs available through CAP within 90 day of the annual election period or, after the expiration of 90 days following the election period, without 80 days advance written notice to all participating physicians. Finally, physicians should have the right to opt out of CAP should a vendor fail to make proper disclosures or fail to make drugs available that the physician determines are medically necessary for the treatment of his/her patients.

"Statutory Requirement Concerning Claims Processing"

A. Physician Responsibilities and Burden

Under the proposed rule, 42 C.F.R. §414.908, physicians will be given the opportunity to select an approved CAP vendor on an annual basis. Physicians must complete and sign a CAP election agreement. In addition, the physician will be required to submit a written order or prescription to the approved vendor. CMS is proposing that each drug order be accompanied by the following information:

* Date of order
* Beneficiary name
* Physician identifying information
* Drug name
* Strength
* Quantity ordered
* Doses
* Frequency/instructions
* Anticipated date of administration
* Beneficiary Medicare information/Health insurance (HIC) number
* Supplementary Insurance info
* Medicaid info
* Shipping address
* Additional patient info: date of birth, allergies, Ht/Wt/ICD-9 etc.

CAP participating physicians must also provide information to the approved vendor to facilitate collection of applicable deductibles and coinsurance, notify the vendor when a drug is not administered, agree to file a "clean" Medicare claim within 14 days of the date of drug administration that includes the name and HCPCS code of the drug administered, the prescription number for each drug administered, and the date of service, and agree to submit an appeal accompanied by all required documentation necessary to support payment if the participating CAP physician's drug administration claim is denied. Physicians will also have to maintain a separate electronic or paper inventory for each CAP drug obtained.

No provision is made to compensate the physician for any of the above activities. Yet, if a vendor is not paid on claims, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician and if the problem persists, the vendor may ask the carrier to investigate the physician's performance and recommend the suspension of the physician's CAP election agreement. While the proposed rule does provide for reconsideration and appeal of a physician's exclusion, if the carrier's decision is ultimately upheld, "CMS publishes a final reconsideration determination against the participating CAP physician in the Federal Register." Proposed 42 C.F.R. § 414.916(b).

Comment: The CAP process creates a dramatic and operationally significant change in how physicians acquire Medicare Part B drugs. When ordering from a non-CAP vendor, physicians stock a single, centralized, inventory. CAP requires each practice to order drugs and track inventory on a prescription basis for each patient, track the date of administration, bill claims within 14 calendar days of administration and share information with vendors to assist them in collecting co-payments.

For a program that was designed to get physicians out of the drug acquisition business, CAP does little to lessen the administrative burden on physicians. In fact, we believe that it **significantly** increases the burden. Moreover, the reward for signing on as an unpaid agent of the vendor potentially is investigation and a public pronouncement of exclusion from the program.

Recommendation: CMS must restructure CAPS' proposed claims process and tracking requirements to significantly reduce the administrative burden on physicians.

B. Written Order or Prescription

The statute (MMA) provides that the contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. The statute further provides that this section does not require a physician to submit a prescription for each individual treatment, or change a physician's flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or course of treatment.

For purposes of CAP, CMS has chosen to interpret the term "prescription" to include a written "order" submitted to the vendor. CMS states its intention not to restrict a physician's flexibility when ordering drugs from a CAP vendor or to require that a physician participating in CAP would order drugs differently from a CAP vendor than he or she would a non-CAP vendor.

Comment: As proposed, a CAP "vendor" will supply pharmaceuticals to a physician's office for a particular beneficiary (patient). The "vendor" then submits a claim with a prescription number for the pharmaceutical agent to a designated carrier. That claim must be matched to a claim filed by the physician that shows the date of administration by the physician. This is not a typical supplier arrangement but rather describes the "filling" or dispensing of a "prescription" for a specific patient.

There are two problems with this approach. First, Federal and state laws make clear that only a licensed pharmacist may dispense a prescription. Second, requiring CAP participating physicians to maintain individual, patient-specific inventories will further increase costs substantially to physicians. Based on the fact that approximately one-third of treatment regimens are switched during the treatment cycle, there will be a significant waste problem that will increase waste disposal costs to physicians and increase drug reimbursement costs to Medicare.

Recommendation: It is clear that the statute (MMA) very specifically uses the word "prescription," which cannot be loosely interpreted by CMS to mean an "order."

C. Order Splitting

CMS proposes allowing the physician to place an order for a beneficiary's entire course of treatment at one time but allow the vendor to split the order into appropriately spaced shipments. According to CMS, the vendor would create a separate prescription number for each shipment and the physician would track each prescription separately and place the appropriate prescription number(s) on each drug administration claim.

Comment: It is unclear how CMS could authorize a vendor to split a shipment of pharmaceuticals needed to treat a patient without the express consent of the physician who orders the drugs. How does the vendor know how to "appropriately" space shipments? Further, allowing the vendor to split shipments creates additional administrative burden for the doctor.

Recommendation: Vendors should be prohibited from splitting shipments unless approved by the physician who orders the drugs.

D. Inventory Resupply

CMS has proposed that drugs acquired under the CAP may be used to resupply inventories but only if the physician can demonstrate all of the following to the Secretary: (1) the drugs are required immediately, (2) the physician could not have anticipated the need for the drugs, (3) the vendor could not have delivered the drugs in a timely manner, and (4) the drugs were administered in an emergency situation.

Comment: The standard for allowing physicians to resupply inventories with CAP drugs is too onerous and does not take into consideration certain common reasons why a CAP drug may not have been used. About one-third of the time, a scheduled treatment for an oncology patient does not happen as planned. This may be due to scheduling issues or, more commonly, the patient's needs change and an alternative regimen is indicated. In most cases, such changes cannot be categorized as "emergencies." Yet, it is highly unreasonable and very costly to require a patient, who has already been examined and tested, to return in another day or two, in order to obtain a new mixture of drugs, rather than obtain treatment from the physician's inventory. **The resupply rules will be especially difficult for rural oncology clinics where patients in debilitated health must travel long distances to obtain treatment. Delaying treatment and requiring patients to return on another day or wait long hours in order to receive new shipments of drugs acquired through the CAP vendor, is an enormous inconvenience to the patient and a cost to the practice. More importantly however, delaying treatment can adversely affect patients' health and ultimately drive up health care costs.**

Recommendation: Physicians should be permitted to resupply their inventories if any one of the four conditions is applicable.

E. Unused Drugs

CMS proposes that, if for some reason, the CAP-acquired drug cannot be administered to the beneficiary on the expected date of administration, the physician would notify the vendor and reach an agreement on how to handle the unused drug, consistent with state and federal law.

Comment: CMS' proposal ignores the fact that most pharmacy regulations indicate that a drug, once dispensed in a patient's name, may not be returned, reused, or reshelved. The conversion of oncology drug inventories from a single, centralized, non-patient specific inventory to a patient-specific, individualized inventory creates the potential for millions of dollars of "waste" from unused and unusable medications.

Recommendation: We understand that the requirement that a vendor only provide drugs to a participating CAP physician prohibition based upon a prescription is statutory. Nevertheless, we urge CMS to work with Congress to address impediments to a viable CAP program.

F. Uncompensated Costs

One of the goals of CAP is to reduce the financial burden of drug acquisition on physician practices. However, as long as chemotherapy and other therapies to treat cancer are incident to a physician's services, physician practices will still incur costs associated with drug handling and inventory. The preamble to the proposed rules, for example, states, "the drug and prescription number would be shipped to the physician and would be maintained until the date of drug administration." However, no provision is made to compensate the physician for these costs.

Comment: At a recent Med PAC meeting, Med PAC staff identified the costs of drug handling and inventory in the hospital outpatient setting at 26% to 28% of drug costs. Oncology practices have long maintained that drug handling and inventory costs run about 12% of total drug purchase expenditures. While the CAP program does not eliminate these costs for oncology practices, physicians are not compensated for these costs under any other fee schedule.

Recommendation: CMS must recognize and compensate oncologists for the costs of drug handling and inventory.

G. Furnish as Written

CMS proposes that when a CAP participating physician has determined that it is medically necessary to use another brand of product within the HCPCS or a product with an NDC that is not being furnished by the vendor, that the physician be allowed to bill for the drug under ASP. The physician would place a "furnish as written" modifier on his or her claim form and bill the Medicare carrier for the drug and the administration fee.

Comment: We support the CMS proposal to permit physicians to obtain a drug under the

ASP methodology in "furnish as written" cases when medical necessity requires that a specific formulation of a drug be furnished to the patient and the vendor has not been contracted to furnish a specific formulation of a drug or product defined by the product's NDC number. However, we are concerned that physicians are still subject to post payment reviews and carrier determinations that a specific NDC number was not medically necessary. This process takes the medical decision-making completely out of the physician's hands, yet it is the physician who holds the responsibility and the liability for the quality and effectiveness of drugs used for patient care, and has access to the full information.

Recommendation: CMS must make clear that "furnish as written" orders are reviewed under the same standards and process used under Medicare Part B for non-CAP drug acquisitions.

H. Physician Choice of Drug Categories

CMS is seeking comments on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether the physician should be allowed to choose the categories of drugs he wishes to obtain from the vendor.

Comment: CAP vendors may create formularies that are inconsistent with the physician's preferred medical practice, or may ignore certain variations in drug approvals or indications within categories. Oncology care is so complex that without the flexibility to deselect certain categories, quality and patient access risks increase dramatically. Furthermore, promoting choice will increase competition among vendors and should have a positive impact on quality and price.

Recommendation: COA strongly recommends that physicians be given a choice of which categories of drugs to obtain from a particular CAP vendor. There is no basis for implementing formularies.

I. Collecting Beneficiary Co-payments

The statute requires that the vendor bill Medicare and the beneficiary, and that the beneficiary may not be billed until after the drug has been administered to the beneficiary by the physician, who has filed a claim for the drug administration. CMS is proposing that the vendor be allowed to bill the beneficiary and/or his or her third party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and the Medicare program makes final payment.

Comment: Despite the impact on cash flow, community oncologists generally are reluctant to refuse to treat a patient who cannot afford to pay a co-payment. Vendors, however, are not ethically or legally responsible for the course of a patient's treatment. If a vendor is unable to collect co-payments from a patient, nothing prohibits the vendor from stopping delivery of drugs to the physician's office. Allowing vendors to stop

delivering drugs to an outpatient setting is likely to endanger patients or force them into more costly in-patient settings for treatment. Further, physicians could be exposed to liability if the physician is unable to complete a course of treatment because a vendor is refusing delivery.

Recommendation: The final rule must make clear that vendors cannot refuse to deliver drugs because they are unable to collect co-payments. Alternatively, if CMS does allow vendors to stop delivering drugs, this must be made very clear to physicians during the CAP election period that the vendor may suspend treatment to any patient not paying their co-insurance. Additionally, physicians must be permitted to immediately opt out of CAP and obtain drugs through the ASP system in any single case where a vendor has decided to not ship drug(s) for a patient not paying the Medicare co-insurance.

"Contracting Process-Quality and Product Integrity Aspects"

Sections 1847B(b)(2)-(3) of the MMA makes clear that vendors must meet financial and quality of care requirements aimed at assuring the stability and safety of CAP. The statute also provides that vendors have sufficient capacity to acquire and deliver drugs within a geographic area, to deliver drugs in emergency situations, and to ship drugs at least five days a week. The MMA also requires that the criteria for awarding vendor contracts include the vendor's ability to ensure product integrity. CMS correctly notes in the preamble that physicians would be reluctant to participate in CAP if they have little confidence that CAP vendors would be reliable and provide quality CAP products. The preamble further states that CMS seeks to "define a set of overall financial and quality standards that would ensure that reputable, and experienced vendors are chosen to participate in CAP and states we propose that CMS be allowed to suspend or terminate a vendor's contract if the vendor falls out of compliance with any of these quality requirements."

Unfortunately, the proposed rule does not identify those standards. Rather, the proposed rule states only that CMS will select approved vendors based upon certain criteria including but not limited to the "ability to ensure product integrity," "financial performance and solvency," and "record of integrity and the implementation of internal integrity measures." Proposed rule at 42 C.F.R. § 414.908(b).

On the other hand, proposed rule 42 C.F.R. §414.916(d) provides that issues regarding quality and service that relate to the vendor's performance raised by the participating CAP physician are treated through the vendors own internal grievance process. If the approved vendor does not resolve a quality issue to the participating CAP physician's satisfaction, the participating CAP physician may escalate the matter to the designated carrier. Unlike the unpaid physician who is subject to investigation and exclusion, CMS merely provides that the "designated carrier attempts to develop solutions that satisfy program requirements and the needs of both the participating CAP physician and the approved vendor." Proposed 42 C.F.R. §414.916(d).

Comment: Vendors are being paid to delivery highly volatile and, at times, toxic drugs to physicians who need them to treat critically ill patients. It is essential that vendors be held to the highest standard for quality and performance. Physicians, who will be dependent on the vendors to obtain these drugs, need to know that when complaints are raised about poor quality and performance that vendors and CMS will take them seriously. It is unrealistic to believe that physicians will participate in CAP if there is no effective process for addressing quality concerns and if they believe they have no recourse if a vendor is not performing as expected. It is unsettling and contrary to good business practice that physicians are locked into their choice of the CAP vendor(s) for a year regardless of performance and quality.

Recommendation: CMS must strengthen the rules pertaining to quality and performance standards of vendors and clarify the procedures that will be used to investigate allegations involving the poor performance of vendors. Vendors who fail to perform should be subject to investigation and sanction, up to and including exclusion from the program.

We also recommend that CMS develop standard "hold harmless" language for the CAP election agreement that ensures that participating physicians are held harmless for the negligence and non-performance of CAP vendors.

Finally, CMS must make clear that physicians may disenroll from CAP at any time, especially in cases of quality non-performance.

In summary, we find the proposed regulations governing the CAP incomplete. Further, we believe the proposed regulations will be too costly to a small practice to implement unless the increased costs of ordering and tracking drugs by prescription number, keeping a separate inventory record by pharmacy order, etc are compensated to the practice. We believe that the proposed regulations will not be found to be satisfactory to medical oncologist devoted to providing high quality, patient focused care to their patients. We do not plan to use the CAP in any form. We will use the ASP system if it proves to be economically sustainable. If the ASP system alternative fails the economic sustainability test, we will order chemotherapy administration for our Medicare patients at a hospital setting. While this will be more costly to the Medicare program and to the patient and much more inconvenient to the patient and the physician, at least our practice will not go out of business by participating in the CAP as proposed.

Sincerely,

Kevin P. Mulvey, M.D., Managing Member
Scott D. Taylor, CPA, Administrator
Hematology & Oncology Associates of Eastern Idaho, PLLC
2330 Desoto Street
Idaho Falls, ID 83404
208 552-1410

Submitter : **Mr. Theodore Okon** **Date: 04/26/2005**

Organization : **Community Oncology Alliance**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached document.

CMS-1325-P-E8-Attach-1.doc

Community Oncology Alliance
Dedicated to high quality, affordable, and accessible cancer care

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Memphis, TN 38120
(901) 683-0055
communityoncology.org

HAND-DELIVERED

April 26, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS – 1325-P, Comments on the Notice of Proposed Rulemaking for the Competitive Acquisition of Outpatient Drugs and Biologicals under Part B

Dear Dr. McClellan:

The Community Oncology Alliance (COA) welcomes the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rules implementing provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requiring establishment of a competitive acquisition program (CAP) for certain Medicare Part B drugs.

As you are well aware, COA represents the interests of community cancer clinics, where over 80% of Americans battling cancer are treated. COA was formed specifically to support and advocate for Medicare payment reform that is balanced, appropriate, and reflective of the realities of delivering modern-day cancer care.

Previously, we provided CMS with extensive comments regarding the impact of changes in the Medicare physician fee schedule and reimbursement methodology for Part B drugs on cancer treatment. We understand that CAP was a part of the same payment reform package and that CAP was intended to help, not hurt, community cancer clinics by reducing the financial burden of drug acquisition. We also understand that CMS did not create CAP, but is mandated by the MMA to implement it.

Regrettably, we have concluded that CMS' proposed design for CAP exacerbates CAP's statutory flaws.[1] The resulting program, conceptually and operationally, can best be described as, "bad medicine and bad economics." In terms of "bad medicine," CAP:

- Gives vendors, not oncologists, control over what drugs are available, when and how they will be delivered and deprives oncologists of the flexibility to modify treatments as medically necessary.

[1] The statute prohibits a CAP vendor from delivering drugs or biologicals to a selecting physician except upon receipt of a prescription, and the vendor's payment is conditioned upon the administration of the drug. 42 U.S.C. Section 1395w-3b. As a result, electing physicians will be required to maintain paper or electronic individual inventories of drugs and biologicals. Beyond the administrative burden, individual inventories create the potential for millions of dollars of "waste" from unused and unusable medications.

- Once oncologists elect a CAP vendor, they will be locked-in to their contracts for a year, irrespective of vendors' performance.
- Gives vendors the responsibility for collecting patient co-payments and allows them to discontinue delivery of cancer drugs to oncology clinics for specific patients if co-payments are unpaid or uncollected. Putting CAP vendors between patients and their oncologists and nursing team creates unacceptable medical and legal risks to both patients and treating physicians.
- Forces patients to return for extra visits because ordering and resupply rules are too rigid. To a person fighting cancer, every second spent out of a cancer clinic living a normal, productive life is an extremely important part of the healing process.

Given Congress' timetable for CAP implementation, CMS has not had adequate time to consult with practicing community oncologists about the design of CAP. The concept outlined in the MMA may make sense in competitively bidding routine prescription drugs, but CAP simply ignores the reality of delivering complicated, chemotherapy regimens, most involving multiple, toxic drugs.

In terms of "bad economics," CAP is oblivious to the financial realities of cancer treatment in 2005. Some of the major "economic" problems are:

- Cancer care in 2005 involves increasing use of new brand drugs versus generics. There is no incentive or reason for brand manufacturers to competitively bid their drugs outside of formulary that in turn restricts access to care.
- CAP will place new administrative burdens on community cancer clinics. In addition to onerous claims process and tracking requirements, clinics will have to manage individual patient drug inventories under CAP. These new burdens are not compensated by Medicare and will increase financial pressures on CAP participating clinics.
- If community cancer clinics are unable to obtain medically necessary drugs to treat their patients or if they are unable to absorb the additional financial burden imposed by CAP, cancer patients will be sent to hospitals where treatment will be more costly.

We are extremely concerned that CMS is proposing to implement CAP first in cancer care without any cost or risk analyses. After all, we are dealing with the treatment of cancer, where life and death hangs in the balance. The current cancer care delivery system has evolved over the past 15-20 years when cancer treatment shifted from hospital-based to the outpatient, community setting. Easily accessible cancer care, combined with earlier disease diagnosis and more targeted therapy, have actually decreased the cancer mortality rate in recent years. CAP changes a time-tested, efficient delivery system with an untested concept. It is akin to allowing new cancer drugs to be introduced to clinical use without rigorous FDA clinical trials, analyses, and approval.

We are providing our comments to you in a separate document, which is attached to this letter. Section I is a summary of our major concerns. Section II includes an extensive, section-by-section analysis. Where appropriate, we have offered specific recommendations.

In closing, we urge CMS to postpone the implementation of CAP until such time as a workable framework can be developed and extensive analysis is conducted. Such actions can only be achieved if CMS takes the time to listen to community oncologists and others physicians who treat patients under Medicare Part B. As a fellow physician, you well understand our commitment to our patients to provide effective, medically necessary treatment and our concern that CAP increases burden without improving care.

Thank you again for your consideration. We welcome the opportunity to answer your questions or provide you with additional information regarding our concerns. We will make ourselves available to meet with you as soon as possible to discuss the CAP program and other critical issues facing community cancer clinics.

Sincerely,

Leonard Kalman, MD, President
Frederick M. Schnell, MD, Vice President
Linda Bosserman, MD, Secretary
Community Oncology Alliance

cc: Mr. Ira Burney (CMS/OL)
Mr. Marc Hartstein (CMS/CMM/HAPG)
Mr. Herbert Kuhn (CMS/CMM)
Mr. Bob Loyal (CMS/OFM/PIG/DPE)
Mr. Jim Menas CMS/CMM/HAPG/DPS)
Ms. Carolyn Mullen (CMS/CMM/HAPG/DPS)
Mr. Stephen Phillips (CMS/CMM/HAPG/DPS)
Ms. Liz Richter (CMS/CMM/HAPG)
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CMS File No. 1325-P

Comments on the Proposed Rules Implementing the Competitive Acquisition Program (CAP) published in the Federal Register on March 5, 2005

Prepared by the Community Oncology Alliance

April 26, 2005

Part I - Introduction and Summary

On March 4, 2005, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule implementing CAP for Medicare Part B drugs. The CAP program was established by the MMA and is intended to provide physicians with an alternative way of obtaining Medicare Part B drugs. Under CAP, beginning January 1, 2006, physicians who choose to participate in CAP will obtain Medicare Part B drugs from vendors who have been selected through a competitive bidding process. Under CAP, vendors, not physicians, are responsible for billing Medicare carriers and collecting beneficiary co-payments.

According to CMS, while CAP *may* provide opportunities for Federal savings to the extent that aggregate bid prices are less than 106 percent of the average sales price (ASP), an important goal of CAP is to eliminate the financial burden on physicians by providing an alternative means for physicians to obtain Part B drugs. In other words, CAP is supposed to provide an alternative for physicians who do not want to be in the business of acquiring and billing both Medicare and patients for cancer drugs.

The Community Oncology Alliance (COA), however, analyzed the proposed rule and identified a number of serious concerns regarding CMS' approach that render the program unworkable for oncologists. COA's detailed analysis and recommendations are set forth in Part II of this document. COA's major concerns are summarized as follows:

--- CMS must have CAP operational by October 1, 2005, the beginning of the annual election period. Yet, the proposed rule reflects that CMS is still very much in the information gathering stage of program development and has not yet even fully conceptualized critical operational features or implementation tasks such as developing a pricing methodology and designing and running a bidding process. The rush to meet deadline, however, seriously compromises CAP's chance for a successful launch and further, compromises the public's opportunity to comment on proposed rules as required by the Administrative Procedure Act (APA).

--- CMS' proposed claims processing system fails to relieve physicians of the cost and burden of purchasing drugs. In fact, it is more burdensome since physicians must not only file detailed claims, they also must track each drug by prescription, maintain at least a paper or electronic inventory of drugs for each patient individually, notify the vendor when a drug is not administered, provide the vendor with information to assist in the collection of deductibles and co-insurance and pursue appeals when a claim is denied – all without compensation.

---- Physicians will be locked into a contract with a CAP vendor for a year with little or no recourse if the vendor fails to perform and provide the level of service required to meet the needs of a busy oncology clinic. Oncologists rely on the timely delivery of quality drugs and biologicals to treat patients who are receiving complicated drug protocols which must be administered within a slotted timeframe to ensure efficacy of the treatment. If a vendor fails to perform, physicians must be able to immediately terminate their CAP elections with the option of either purchasing the drugs themselves or electing a new CAP vendor.

---- The proposed rule overly restricts a physician's choice of and access to medically necessary drugs. Among other issues, for multi-source drugs, the proposed rule would allow CAP vendors the option to choose which drug(s) within the class will be provided. CMS also is considering requiring physicians to obtain all categories of drugs from a particular CAP vendor (rather than allowing the physician to choose the categories of drugs he or she wishes to obtain from the vendor). Finally, the proposed rule severely limits when and under what circumstances a physician can use CAP drugs to resupply inventory and fails to provide timely access to drugs in an emergency.

---- CAP vendors, who are neither legally nor ethically responsible for the course of a patient's treatment, will be responsible for collecting Medicare copayment from secondary insurers or from patients. Should CAP vendors be unable to collect co-payments, nothing in the statute or proposed rule prohibits vendors from stopping delivery of the drugs to the community cancer clinic.

Part II - Section by Section Analysis and Recommendations

1. Overview of CAP

Implementation Tasks and Timetable

The MMA provides that CAP is to be effective on January 1, 2006. Prior to issuance of the proposed rule, CMS engaged in several activities to help the agency design and implement CAP. Specifically, CMS hired a contractor to obtain basic information, develop alternative proposals, and consult with stakeholder groups. CMS also conducted one Special Open Door Listening Session on April 1, 2004, established an electronic mailbox, and issued a Request for Information, which yielded 15 responses. Nevertheless, as noted below, the proposed rule suggests that CMS is still very much in the information gathering stage and is still deliberating various options regarding basic program operations. As a result, the proposed rule lacks specificity regarding a number of key program requirements.

Beyond the need to identify key program requirements, CMS has identified a laundry list of activities that must be completed prior to CAP's effective date, including designating or developing quality, service, and financial performance standards for vendors; creating a pricing methodology; designing and running a bidding process from solicitation through contract award; providing physicians with an opportunity to elect to participate and select a vendor; educating beneficiaries about the program; and conducting other activities specified in the statute and

described in the proposed rule. In reality, however, the CAP bidding process and the selection of vendors must be completed by fall, 2005, which is the beginning of the first annual election period.

Comment: With only eight (8) months before CAP's effective date, and less than five (5) months before the beginning of the first annual election period, COA is concerned that CMS does not have adequate time to deliberate and reach closure on key program requirements *and* complete all of the tasks necessary to initiate CAP. Furthermore, CMS' interest in broadly soliciting input on very basic issues at this stage in the CAP implementation process suggests that CMS lacks sufficient information and understanding of the drug acquisition process and its impact on community cancer care and the delivery of cancer treatment to formulate viable proposals for the CAP program.

Recommendation: While we are cognizant that Congress decreed that CAP should be effective on January 1, 2006, we strongly urge CMS to take the time it needs to fully understand how CAP can best be structured to attain Congress' objectives and benefit physicians without compromising access to drug therapies and treatment. Further, to ensure an effective launch with adequate vendor and physician participation, CMS must delay the effective date of CAP to such a time

2. Categories of Drugs to be included under the CAP

a. Categories of Drugs to be included in CAP

The MMA provides some flexibility in the development of CAP by giving the Secretary of the Department of Health and Human Services (HHS) the authority to select appropriate categories of drugs and appropriate geographic areas for the program. CMS proposes three phase-in options:

Option 1 – Under Option 1, CMS would initially implement CAP for a limited set of drugs that are typically administered by oncologists. Drugs typically administered by other specialties would be included over the next few years. CMS believes that one advantage of this approach is that it allows CMS to focus implementation efforts on one specialty with a more homogeneous set of concerns and issues. Also, by limiting the targeted drugs to those typically administered by oncologists, the physician education process would be streamlined and potentially more effective. Finally, oncologists use a high proportion of the physician-administered drugs that could be included under CAP, therefore making the program more attractive to potential vendors. A potential downside is that a focus on oncology drugs may be too narrow and would deprive other physicians of the opportunity to participate.

Option 2 – Under Option 2, CMS would choose a limited set of drugs that are typically administered by one or more physician specialties that use Part B drugs less intensively. Such an approach would allow operational issues to be addressed more gradually, but may restrict the potential benefits of the program. Further, a restricted approach may not elicit sufficient response from potential vendors.

Option 3 – Under Option 3, CAP would be implemented for all Part B drugs that are furnished incident to a physician's service regardless of specialty.

CMS states that it is not proposing any particular option at this time but is actively considering all of these options and is encouraging recommendations on other approaches for further analysis. CMS further states that it may adopt one of the options described above, or an option brought to its attention through the comment process, in the final rule. Importantly, the categories that are established for physicians to select will be the same categories that would be open for bids of potential vendors. Thus, for example, if a category embracing all drugs typically administered by oncologists is established, vendors would bid on all HCPCS codes contained in the category and a physician who elects to participate in CAP would be electing to acquire that category from the vendor.

Comment: CMS' approach violates the Administrative Procedures Act (APA) requiring that agencies must publish a notice of proposed rulemaking in the Federal Register that provides interested persons with an opportunity to participate in the rule making through submission of written comments. 5 U.S.C. § 553. It is well established that a notice of proposed rulemaking must provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully.[2] Here, CMS has made no specific proposal regarding the phase-in of CAP. Instead, CMS has offered three options and is seeking additional ideas from interested entities. While CMS' interest in soliciting new ideas is appreciated, contrary to CMS' own statement, it cannot adopt a proposal without giving the public the opportunity to comment on it.

Recommendation: Once CMS has decided what "phase-in" approach it will take, a second notice must be published in the Federal Register to allow for public comment before the proposal can be adopted as a final rule.

b. Allowing Vendors to Limit Availability of Drugs within Categories (i.e., formularies)

While vendors will be required to bid on all HCPCS codes within a category, (e.g. drugs used by oncologists), CMS is proposing that vendors not be required to provide every National Drug Code associated with a HCPCS code.[3] In effect, this gives a vendor permission to establish a formulary by choosing which drugs it will make available through CAP.

Comment: Cancer treatment is complex and poses many risks to patients. Although oncology drugs may be in the same class and category, they are not fungible. Active ingredients, for example, may be similar, but inactive ingredients may act quite differently when combined with other drugs in a complex, multi-treatment regimen. Certain drugs may be less effective or more costly to administer (e.g., the drug takes extra time to reconstitute, or fails to mix properly — leaving particulate matter and needed treatment, at the bottom of the bag instead of in the patient). Furthermore, different drugs within the same class or category can have different FDA

[2] Florida Power & Light Company v. U.S., 846 F.2d 765, 269 U.S. App. D.C. 377 (CADC 1988), cert denied 109 S.Ct 1952, 490 U.S. 1045, 104 L. Ed. 2d 422.

[3] Although this proposal is discussed in the preamble to the proposed rule, it is not included in the actual text of the proposed rule.

approvals and different indications for use. A prime example is Procrit and Aranesp. For certain types of treatments, some may consider these drugs to be interchangeable; however, the drugs are different because each drug has a different indication for use. Similarly, interferon drugs, while in the same category, also have different indications and FDA approvals.

When a health insurer or prescription drug plan limits access to drugs through a formulary, certain safeguards generally are required to ensure that patients are assured access to medically necessary drugs and that formularies are not overly restrictive or driven solely by pricing. For example, under Medicare Part D, formularies must be developed by Pharmacy and Therapeutics (P&T) committees. Formularies must also be non-discriminatory and must provide for exceptions and appeals. Finally, prescription drug plan sponsors are prohibited from making certain formulary changes and if formulary changes are made, plans must provide notice or a one-time supply to assist the beneficiary through transitions.

Unlike Medicare Part D, however, CMS has not proposed any minimum standards or safeguards to govern which drugs must be covered by CAP vendors within a designated category of drugs. If vendors are allowed to restrict access or are allowed to change the drugs offered without notice to the participating physicians, physicians are unlikely to elect to participate in CAP. For those that do elect to participate, if formularies become too limited, they will be forced to resort to "dispense as written" specificity for drugs and work outside of CAP through the ASP program, incurring cost and additional effort on all sides. (See additional comments below regarding CAP Operations.) Finally, we note that while CMS states in the preamble to the proposed rule that, upon request, vendors will be required to provide potential physician participants with specific information about the NDCs within each HCPCS code that it provides and that this information must also be disclosed to CMS as part of the bidding application, the proposed rule contains no such provisions.

Recommendation: The final rule must make clear that formularies are not permitted. Further, the final rule should provide that during the annual election period and upon request thereafter, a CAP vendor must fully disclose each drug that the vendor will make available pursuant to its CAP contract. In addition, vendors must be prohibited from making any changes in the list of drugs available through CAP within 90 days of the annual election period or, after the expiration of 90 days following the election period, without 90 days advance written notice to all participating physicians. Finally, physicians should have the right to opt out of CAP should a vendor fail to make proper disclosures or fail to make drugs available that the physician determines are medically necessary for the treatment of his/her patients.

c. Exclusion of drugs

Section 1847B(a)(1)(D) of the Act gives the Secretary authority to exclude competitively biddable drugs and biologicals from CAP on grounds that including those drugs and biologicals would not result in significant savings or would have an adverse impact on access to those drugs and biologicals. While the preamble to the proposed rule states that CMS has made no findings regarding these two issues at this time, and the rule merely tracks the statutory language without elaboration, neither the preamble nor the rule identify how CMS intends to monitor either savings or adverse impact on access.

Submitter : Mr. Venty Butts **Date:** 04/26/2005

Organization : Montgomery Cancer Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please think aobut the actions you will take the impact it will have on patients. Nothing good can come out of CAP. This is ill planned and poorly designed. It is be a total disaster if this program is implemented.

CMS-1325-P-E9-Attach-1.doc

Comments to CMS
Venty Butts
Mandatory Vendor Imposition/ Competitive Acquisition Program

There are numerous concerns that I have about CAP. As an administrator for an outpatient cancer facility I think I have insight that would be valuable to you as you evaluate this new delivery system of drugs for chemo patients. I believe that I am a very fair and balanced individual and although I think ASP + 6% is not a true reflection of the real cost and adequate payment to cover the cost, I support changes to the system. What I must disagree with is a program that will create a nightmare for every patient and every provider who opts to use CAP. Here are my concerns:

- Administrative nightmare- no controls and high risk
- Patient inconvenience created by not knowing if treatment is appropriate that day until with out lab test to confirm.
- Cost to handle drugs through the vendor program. Drugs mixing that must be done prior to treatment, the practice should be paid for the service.
- The liability of using drugs that are improperly managed or mixed should not rest with the MD.
- The changing of a regimen when a patient is not responding to a particular regimen is another huge problem.
- Paper work for the CAP vendor. Why should the practice be responsible for doing this?
- Numerous cost to practice to be in CAP with no advantage.

The list could go on and on. I can not think of one reason why CAP would work except for the cost of managing and buying inventory. The system will fail if these issues are not readdressed and all of this thought through. Please don't put cancer chemo and patients at risk in a program that can not work. Act wisely. This program will fail because it is not reasonable nor logically. I hope that for every cancer patient, you think about what is at stake for them. This is their life you are dealing with. They deserve your best efforts and attempts. Don't do anything that you would not accept for yourself or your family if you or they needed chemotherapy.

Sincerely,

Venty Butts

Submitter : Dr. Brendan Fox

Date: 04/26/2005

Organization : American Urological Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-1325-P-E11-Attach-1.doc

American
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April 26, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-1325-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: CMS-1325-P – Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B.

Dear Dr. McClellan:

On behalf of the American Urological Association (AUA), representing 10,000 practicing urologists in the United States, I am pleased to submit comments on the March 4, 2005 proposed rule on Medicare's competitive acquisition program (CAP) for outpatient drugs. We realize that CMS faces a difficult task in implementing the CAP, which is a new and complex competitive bidding program that must to a large degree fit within existing Medicare program rules and processes.

We appreciate CMS's efforts to develop rules that would be as simple as possible for physicians and Medicare beneficiaries while still fitting within Medicare's current laws and claims processing capabilities. **However, this rule as proposed falls far short of those stated goals. The AUA believes that most urology practices will not choose to participate in the CAP as currently proposed, as is it too confusing for beneficiaries and physicians, it is burdensome and it creates significant administrative expenses that are simply not reimbursed. Therefore, our comments offer suggestions for improvements to the proposed CAP process that may increase the likelihood of greater physician participation in the CAP.**

Also, many parts of the proposed rule were not actual proposals, but rather a list of possible options along with the advantages and disadvantages for choosing those options. In addition, there are still many unanswered questions about this complex new program, and there is a very short time frame between the comment due date and the implementation of the CAP. **Because of this, in response to proposed rule comments, we urge CMS to publish an interim final rule instead of a final rule.**

SUMMARY

- CMS should publish an interim final rule instead of a final rule

- CMS should not phase-in the drugs that are included in the CAP, but should implement the CAP for all part B drugs that are furnished incident to a physician's service at the onset of the program on January 1, 2006. But, if CMS does choose to phase in CAP drugs for 2006, CMS should include at the very minimum any drugs that urologists and other physicians are currently not able to buy at or less than 106 percent of ASP

- We urge CMS to structure the CAP so that it could be a viable solution for physicians who are not able to purchase bladder cancer drugs at 106 percent of ASP

- To give the largest number of urology practices the option of using the CAP if they so desire, we urge CMS to place urology drugs in categories that are as narrow as possible

- However the drug categories are ultimately structured, to ensure that all Part B drugs are available to Medicare beneficiaries in the physician office setting, the CAP should provide a safety net for drugs on which physicians are suffering financial loss under the ASP payment system

- CMS should determine the appropriate phase-in for competitive acquisition areas that are included in the CAP based on the initial vendor response. However, in any phase-in scenario, CMS should work to ensure that patients in rural areas have access to drugs that physicians are not able to buy at less than 106 percent of ASP

- We urge CMS to reconsider many of the elements it has proposed for claims processing and to simplify the process as much as possible to alleviate the administrative burden on physicians.

- CMS should not require physicians to obtain from a CAP vendor all categories of drugs that the particular CAP vendor provides, but should allow physicians to choose which drug categories to obtain from their vendor.

- The prices that CAP vendors pay for drugs should be excluded from drug manufacturers' quarterly reporting of average sales price (ASP) data

- CMS must explore efficient alternative methods that are not linked to drug administration claims by which providers can verify drug administration to vendors. Also, the vendor payment should not be driven by the filing or payment of a provider's claim for administration.

- Assuming that a physician has their own stock outside of what has been ordered from the CAP vendor, the process for emergency situations could be useful to physicians as long as CMS defines emergency situations broadly enough to incorporate unanticipated situations. Also, there must be some bright-line guidance on the exact method of accounting for the

substitution process.

- Unless some mechanism is established to reimburse physicians for extra administrative costs associated with the CAP, physicians will have no incentive to participate
- Regarding the proposal that physicians must submit drug administration claims within 14 days to participate in the CAP, CMS should expand this to 30 business days
- The data elements proposed to be included in a physician's order for a drug should be limited to what is necessary for a regular prescription
- CMS should clarify the ordering process for drugs that come in multi-use vials
- The CAP vendor should supply a separate storage unit to each contracted provider as is currently done in the commercial drug vending market
- The process for what to do about drugs that are not administered on the expected date is particularly burdensome and will be a major hindrance for physicians who want to participate in the program, and it should be simplified
- The dispute resolution process for physicians should be explained in more detail
- Physicians should be able to choose to opt out of the CAP at any time during their annual election if there are egregious service-related issues

OVERVIEW OF THE CAP

As CMS points out in the general overview of the CAP, there are many tasks to be completed prior to implementation of the program on January 1, 2006. CMS also initiated several activities prior to issuing the proposed rule, including awarding a contract to Research Triangle Institute (RTI) to obtain information and develop alternatives regarding CAP implementation, conducting a Special Open Door Listening Session on April 1, 2004, establishing an electronic mailbox for comments on the CAP program and issuing a Request for Information (RFI) on December 13, 2004.

As part of its contract, RTI consulted with groups, including the AUA, to obtain input on CAP implementation, and we appreciated the opportunity to work with RTI and to provide input early in the process. **However, given the tight time frame for implementing this new and very complex program, and given that CMS has already initiated many activities surrounding the CAP, we implore CMS to give serious consideration to proposed rule comments by affected specialties.** While the RTI discussions and other activities that took place before the rule's publication were helpful, many concepts in the proposed rule were unknown at that time. **Therefore, we expect that proposed rule comments will be weighted equally with discussions based on these previous activities.**

- **Responses to RFI**

It is somewhat alarming that CMS only received 15 responses to its December 13, 2004 RFI to assess the public's interest in bidding on contracts to supply drugs for the CAP. CMS stated in the proposed rule that "most responders indicated a willingness to provide selected Part B drugs on a national basis" and that "In the specialty areas of oncology, hematology, internal medicine, infectious disease, urology, rheumatology and obstetrics/gynecology, several responders indicated a willingness to provide the most costly and the most frequently used drugs in these areas." However, no definition was given of what constitutes the most costly and most frequently used drugs and no examples were given for urology.

This is concerning because there are some urology drugs that are used less frequently than others but are nevertheless vital in the treatment of urological conditions such as interstitial cystitis and bladder cancer. We are hopeful that the CAP will offer a viable option for acquiring the drugs used to treat these debilitating and deadly diseases, as urologists are not able to purchase these drugs for 106 percent of the average sales price (ASP), which is the Medicare payment under the ASP payment methodology. However, if the drugs are not used frequently enough for vendors to be interested in bidding on them, then the CAP program may not offer a solution to this problem after all.

CATEGORIES OF DRUGS TO BE INCLUDED UNDER THE CAP

- **Phasing in drug categories**

CMS should implement the CAP for all part B drugs that are furnished incident to a physician's service at the onset of the program on January 1, 2006. As CMS points out in the proposed rule, "A potential disadvantage of singling out drugs typically administered by one physician specialty for the initial stages of phasing in the CAP is that the scope of the CAP in the early years may be too narrow to effectively identify issues or concerns for specialties that typically administer drugs not initially included. In addition, the CAP would not initially provide an alternative for physicians in other specialties."

Because each specialty is so different in terms of the drugs used and the patterns of use, all Part B drugs should be included at the onset to learn the most from the introductory year(s) of the CAP. Also, because this is a voluntary program, the number of participants is likely to be limited in the first few years anyway, so limiting the number of drugs included might seriously affect the ability to identify and fix problems during a phase in. Restricting the list of drugs could also reduce the number of bidders if they believe that the market is too limited.

If CMS does not choose to include all Part B drugs in the CAP for 2006, we urge CMS to include at the very minimum any drugs that urologists and other physicians are currently not able to buy at or less than the Medicare payment based on the ASP payment methodology. For urology, these drugs are:

Bladder Cancer Drugs: Urologists Costs vs. Medicare Payment

HCPCS	Descriptor	Units	1st quarter 2005 pymt.	2nd quarter 2005 pymt.	Avg. Cost for Urology Offices
J9031	BCG	per instillation	$118.41	$119.53	$127.26
*J9214	Interferon alfa-2b inj	1 million units	$13.12	$12.98	$13.46
J9291	Mitomycin 40 mg inj	40 mg	$141.14	$144.92	$319.69
J9340	Thiotepa injection	15 mg	$43.57	$43.74	$101.50

*The Medicare payment for J9214 is based on 1 million units. For treatment of bladder cancer, J9214 is usually administered in 50 million units, so that total Medicare payment for the typical dose is $649 and the typical cost is $673.

The CMS Physicians Regulatory Issues Team (PRIT) is maintaining a list of "problem" drugs, or drugs that physicians are unable to purchase at or less than the Medicare payment. We urge CMS staff working on the CAP rule to coordinate with the PRIT to ensure that these drugs are covered under the CAP in 2006. Otherwise, patients who need these drugs will have to pay for them out of their pocket, will be sent to the hospital outpatient department which is inconvenient and more costly or, worst of all—will not receive the treatments they need. Urologists must not be expected to suffer a financial loss to provide these drugs to Medicare patients any longer.

The AUA has forwarded information about the cost of bladder cancer drugs to CMS on several occasions and the AUA also met with CMS last December to discuss possible options for addressing urology offices' inability to cover their costs under the ASP payment system for bladder cancer drugs that are administered in the office. CMS has encouraged specialty societies to help their members identify alternate sources for buying drugs and also to educate their members about how to become better purchasers of drugs. The AUA is currently investigating different possibilities for doing this, and we are attempting to help our members achieve these goals to the degree possible.

Also, the MMA mandates that the Inspector General report to Congress by October 1, 2005 on the adequacy of reimbursement rates under the ASP methodology. The OIG is required to conduct a study on the ability of physician practices in the specialties of hematology, hematology/oncology, and medical oncology of different sizes, especially large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the ASP for the drugs and biologicals.

The AUA contacted OIG staff working on this report to inquire about whether bladder cancer drugs were being included in their study. We were disappointed to find that the OIG is basing its study on a very strict interpretation of the MMA and is not including urologists in its study, even though urologists provide oncology services to their cancer patients. Nevertheless, we did forward information to the OIG about the prices that urology offices are paying for bladder cancer drugs, and urged them to at least acknowledge in their report that specialties other than hematology, hematology/oncology and medical oncology are having trouble purchasing drugs at 106 percent of ASP.

Because there are no other immediate solutions to this problem, we urge CMS to structure the CAP so that it could be a viable solution for physicians who are not able to purchase bladder cancer drugs at 106 percent of ASP.

- **Structure of drug categories under the CAP**

It is evident by the design of the CAP that physicians are likely to favor narrow drug categories while CAP vendors are likely to favor broad drug categories. Therefore, CMS has the difficult job of striking a balance that will allow maximum benefit and encourage participation by both physicians and CAP vendors. For the urology practices that do choose to participate in the CAP, some of them will prefer to acquire all of their office-administered drugs through the CAP. However, some practices will prefer to acquire certain drug categories through the CAP while they continue to buy and bill certain other drug categories under the ASP payment methodology. **Therefore, to give the largest number of urology practices the option of using the CAP if they so desire, we urge CMS to place urology drugs in categories that are as narrow as possible.**

However the drug categories are ultimately structured, to ensure that all Part B drugs are available to Medicare beneficiaries in the physician office setting, the CAP should provide a safety net for drugs on which physicians are suffering financial loss under the ASP payment system. Again, CMS could address this by creating a separate category of problem drugs for each specialty or a large category of problem drugs that includes the problem drugs of all specialties, as vendors are likely to be able to negotiate lower prices than physicians can negotiate for these drugs because they will be buying in larger quantities. As mentioned above, CMS could begin by using the list of drugs that the CMS PRIT has identified as problem drugs.

CMS gives one example in the rule of a possible CAP drug category, which is the *Most Commonly Used HCPCS by Oncologists Defined by Specialty Code 90* (Table 1 in the proposed rule, page 10751). By default, many of the drugs that are used by urologists to treat prostate and bladder cancer are included in this example category, as urologists use oncology drugs to treat urological cancers. However, one of the cancer drugs (J9291, Mitomycin 40) that urologists are not able to purchase at 106 percent of ASP is *not* included in the example, while other drugs that urologists can't purchase at 106 percent of ASP *are* included in the example, because they are also billed frequently by oncologists (J9031, BCG; J9214, Interferon; and J9340, Thiotepa). **Therefore, we urge CMS not to limit the CAP drug categories in 2006 to the example shown in Table 1.**

COMPETITIVE ACQUISITION AREAS

Competitive acquisition areas should be structured to maximize vendor competition and minimize administrative burden while at the same time addressing concerns over timely delivery and proper storage and shipment of drugs to physician offices. Therefore, regional competitive acquisition areas are probably the best compromise, even though that would require national vendors to submit multiple bids, because, as CMS points out, there are existing regional areas that could be transferred to the CAP. For example, multi-state acquisition areas could be established based on existing markets, areas could be structured so that they coincide with the

prescription drug plan regions or areas could be structured to coincide with Part B Medicare Carrier regions.

- **Phasing in acquisition areas**

CMS should determine the appropriate phase-in for competitive acquisition areas that are included in the CAP based on the initial vendor response. However, in any phase-in scenario, CMS should work to ensure that patients in rural areas have access to the problem drugs that were discussed above and are being researched by the CMS PRIT.

STATUTORY REQUIREMENTS CONCERNING CLAIMS PROCESSING

CMS says "it is not our intention to restrict the physician's flexibility when ordering drugs from a CAP vendor, or to require that a physician participating in the CAP would order drugs differently from a CAP vendor then he or she would a non-CAP vendor." We realize that CMS is constrained by the requirements of the statute as well as the existing Medicare claims processing rules. However, the CAP claims process as proposed *would* require physicians to order drugs differently than they currently do and could also have negative implications for patient care and practice flow. The current proposal would also add significant administrative expense for physicians who elect to participate in the CAP.

We urge CMS to reconsider many of the elements it has proposed for claims processing and to simplify the process as much as possible to alleviate the administrative burden on physicians. Otherwise, the excessive administrative costs will discourage participation in the CAP both in the short term and the long term.

For example, urologists currently order drugs in bulk, e.g. 20 or more doses at a time with one phone call, fax or email. Under the proposed CAP rules, physicians will have to order separately for each patient and be responsible for informing the CAP vendor each time a drug is not administered on the expected date of administration. There is no way under the rules that a physician can keep a supply of the drug without each dose being connected to a specific patient. The program creates a substantial administrative burden when patients show up without appointments, cancel appointments or reschedule appointments and for situations where a physician must change drug therapy for a patient during the course of the treatment.

CLAIMS PROCESSING OVERVIEW

CMS proposes that physicians who elect to participate in the CAP should continue to bill their local carrier for drug administration and that, for those drugs that are not included in the CAP, and for drug categories that the physician does not select, the physician would continue to bill and be paid under the ASP methodology. Also, CMS solicits comments on whether physicians must obtain all categories of drugs that a particular CAP vendor provides from the vendor, or whether physicians should be allowed to choose which drug categories to obtain from the vendor.

The AUA agrees that physicians who elect to participate in the CAP should bill their local carrier for drug administration for CAP drugs and continue to be paid for other drugs under the ASP methodology. Also, CMS should not require physicians to obtain from a CAP vendor all categories of drugs that the particular CAP vendor provides, but should allow physicians to choose which drug categories to obtain from their vendor.

Also, the prices that CAP vendors pay for drugs should be excluded from drug manufacturers' quarterly reporting of average sales price (ASP) data. Including vendor prices is counter to the intent of the statute because it gives disproportionate weight to the drugs purchased at volume discounts only attainable by CAP vendors. This would punish physicians who wish to continue buying and billing Medicare for drugs under the ASP payment methodology. This would also undermine the voluntary nature of the CAP and the hybrid drug payment system, as it would eventually force all physicians to choose to participate in a costly and burdensome CAP or to stop administering drugs in the office.

For the CAP, the law requires that the vendor can't collect any applicable deductible and coinsurance from Medicare beneficiaries unless the drug was administered to the beneficiary, and that Medicare can make drug payments only to the vendor and the drug payments are also conditioned on the administration of the drug. However, CMS is proposing that payment to the vendor would be dependent not only upon drug administration, but also upon filing and payment of the drug administration claim. This creates a situation where the physician could be facing pressure from the CAP vendor to file their drug administration claims extremely quickly and even possibly to appeal drug administration claim denials that a physician normally would not pursue based on a cost/benefit analysis. For most drugs, the drug administration payments are much lower than the payment for the drug itself, meaning that the CAP vendor is much more likely to have more incentive to push the physicians to appeal intermittent denials.

- **Another example of additional expenses incurred by physician practices that participate in the CAP**

CMS's proposed claims processing methodology would verify drug administration to the beneficiary by means of a prescription number that would be placed on the physician claim for drug administration and the drug vendor claim for the drug. CMS's claims processing system would then use the prescription number to match the two claims and authorize payment to the vendor. According to CMS, the electronic version of the Medicare carrier claim form has space for a series of prescription numbers, which has not been utilized previously for Part B drugs. As part of implementing the CAP program, CMS would require that vendors and physicians who elect to participate in CAP have the capability of submitting these prescription numbers to CMS in their claims processing systems.

For physician practices not already using prescription numbers, they will incur additional costs that are not reimbursed to work with their internal information systems staff or practice management software vendors to make the necessary changes to submit these data elements to Medicare in a manner consistent with HIPAA transaction guidelines for capturing prescription numbers. **CMS must explore efficient alternative methods that are not linked to drug administration claims by which providers can verify drug administration to vendors.** For

example, hospital systems use barcoding technology to quickly and accurately account for drug administration. CAP vendors should be required to provide such technology as part of the bid qualification.

CMS's proposal that physicians must identify an expected date of administration and then notify the CAP vendor if the drug is not administered on that date is very burdensome, especially because patients frequently change appointments. Under the proposed rule, the CAP vendor would wait until the expected date of administration to submit a claim for the drug, which could become very confusing when, for any number of reasons, the drug is not administered on that expected date. Instead, if the physician could verify drug administration to the vendor after the drug has been administered, the vendor could submit their claim knowing that the drug had been administered and the burden would not be on the physician to inform the CAP vendor every time a drug was not administered on an exact expected date.

- **Partial payments to vendors**

CMS solicits comments on whether there are demonstrable, compelling reasons why CMS should consider making a partial payment to the vendor and what the appropriate percentage of the partial payment should be in cases where the drug administration claim is not received by the CMS claims processing system within 28 calendar days of the anticipated date of administration. If the verification of the drug administration is done more efficiently, the vendor could bill CMS for the covered amount for the drug more quickly and thereby alleviate the need for partial payments. The amount of payment delayed would only be the patient's co-payment amount and deductible. In cases where this could cause an undue burden on the vendor (for example, a predominant secondary insurer goes bankrupt), CMS should consider making partial payments to CAP vendors and should work with vendors to determine the appropriate percentage on a case-by-case basis.

- **Emergency situations**

CMS proposes that in emergency situations drugs acquired under the CAP could be used to resupply inventories of drugs administered by physicians as long as the physician could demonstrate that:

1) The drugs were required immediately
2) The physician could not have anticipated the need for the drugs
3) The vendor could not have delivered the drugs in a timely manner
4) The drugs were administered in an emergency situation

CMS proposes that in emergency situations that meet these criteria, a physician could treat a Medicare beneficiary with a drug from his or her own stock and then order the drug from the CAP vendor, identifying the drug as an emergency replacement. Then, once the drug is received by the vendor, the physician would return it to their own stock. Assuming that a physician has their own stock outside of what has been ordered from the CAP vendor, this process would be useful to physicians as long as CMS defines emergency situations broadly enough to incorporate

unanticipated situations such as changing a patient's course of treatment during an office visit or patients who reschedule appointments for an earlier time.

There must be some bright line guidance on the exact method of accounting for this substitution process that alleviates the fears of physicians who would worry about being accused of filing false claims as a result of inadvertent errors in inventory accounting that could result. In addition, clear instructions must be developed about alternatives should the substitute drug not be in the physician's stock. Emergency situations do occur and CMS is correct in trying to find a way for such occurrences to be addressed, but such an exception must not make an already cumbersome process even more so.

- **Additional administrative costs to physicians**

According to CMS, "We do not believe that the clerical and inventory resources associated with participation in the CAP exceed the clerical and inventory resources associated with buying and billing drugs under the ASP system." The AUA has gathered evidence to the contrary. The CAP by its very nature adds an additional level of bureaucracy by establishing an extra point of contact that physicians currently do not have for acquiring drugs. The physician's administrative responsibilities and costs under this program should only be ones that are accounted for within the practice expense portion of the drug administration service for which the physician is receiving payment. The bidding vendor should be responsible for all other administrative costs involved with inventory tracking, maintaining administration logs, and billing for and collection of patient cost sharing amounts. **Unless some mechanism is established to reimburse physicians for extra administrative costs associated with the CAP, physicians will have no incentive to participate**.

- **Requirement of prompt claim filing for physicians who elect to participate in the CAP**

CMS's proposal that physicians who elect to participate in the CAP will be required to agree to bill their drug administration claims within 14 calendar days of the date the drug was administered to the beneficiary is wholly unreasonable. **We reiterate our contention that the vendor payment should not be driven by the filing or payment of a provider's claim for administration**. Claim filing could serve as a useful function to cross-check the administration and to pass on secondary insurance filing information to the vendor, but it should not be the primary vehicle to alert vendors that drug administration has occurred.

CMS should expand this to 30 business days to allow for extenuating circumstances that may be outside the control of the physician and also to minimize the potential for CAP vendors to hassle physicians about submitting their claims. Physicians currently pay up front for drugs that are ordered monthly or even quarterly and are at risk for that money until their claims are approved. There is no reason why CAP vendors can't be at risk for drug payments for 30 days or more. In addition, if CMS does decide to allow partial payments to vendors, it would alleviate this problem.

- **Process for ordering drugs and process for physician to submit information to contractors**

CMS says that the order transmitted between the physician and the drug vendor may occur in a variety of HIPAA-compliant formats, such as by telephone with a follow-up written order. We discussed above that extra administrative costs should be covered for physicians, but it is also important that the process for ordering drugs and submitting information back to CAP contractors (so that contractors can bill Medicare and collect copays) be user-friendly and include phone, fax and internet. CAP vendors should allow internet ordering and should provide bar-code scanning software to make the process as easy as possible. The process should be structured to be as similar as possible to the way a physician currently issues a prescription.

CMS proposes to require that physicians transmit the following data elements to the CAP drug vendor and that abbreviated information could be sent for repeat patients. **The AUA believes that many of these data elements are unnecessary. Including all of these data elements on a prescription is burdensome, duplicative and unnecessary. The requirements should be limited to what is necessary for a regular prescription. Our comments are included in the table below:**

Data Element	Comment
Date of order	Necessary
Beneficiary name	Necessary
Physician identifying information: Name, practice location, group practice information (if applicable), PIN and UPIN	Physician name and PIN should be sufficient. If the physician has already signed a contract with the CAP vendor, the vendor should have the other information already in their computer.
Drug name	Necessary
Strength	Necessary
Quantity ordered	Necessary
Dose	Necessary
Frequency/instructions	Necessary
Anticipated date of administration	A range should be required rather than an exact date. A 30-day range would be acceptable to account for rescheduled appointments, etc.
Beneficiary Medicare information /Health insurance (HIC) number	Necessary
Supplementary Insurance info (if applicable)	The physician should not be responsible for supplying this information to the vendor, as the physician is already required to fill it out once on the drug administration claim form. The Medicare central claims office should supply this information to the vendor once the prescription numbers have been matched.
Medicaid info (if applicable)	The physician should not be responsible for supplying this information to the vendor, as the physician is already required to fill it out once on the drug administration claim form. The Medicare central claims office should supply this information to the vendor once the prescription numbers have been matched.
Shipping address	This should be supplied to the selected vendor in the initial

	contract and is not necessary on every order.
Additional Patient Info: date of birth, allergies, Ht/Wt/ICD-9, etc.	This should not be required on the order.

Also, clarification on the ordering process for drugs that come in multi-use vials is very important for urology. For example, testosterone cypionate (J1080), which is frequently used by urologists, typically comes in a 10 cc vial, which equates to about 10 injections. It would be a logistical nightmare to order one vial from the vendor and then have to track all the different patients that are given injections from that vial so that you could properly bill Medicare. **A process must be developed to handle such drugs or CMS may want to consider these types of drugs as eligible for exclusion from the CAP.**

- **Inventory**

Although CMS is not requiring separate physical storage of CAP drugs, they are proposing that physicians participating in the CAP be required to maintain a separate electronic or paper inventory for each CAP drug obtained. These are contradictory positions in that the requirement to maintain separate inventory accounting can only be effectively accomplished by maintaining separate physical storage. Otherwise, verification of physical inventory against inventory accounting becomes a logistical nightmare. **The CAP vendor should supply a separate storage unit to each contracted provider as is currently done in the commercial drug vending market.**

- **Billing beneficiaries for deductible and coinsurance**

The MMA requires that the vendor bill Medicare and the beneficiary, and that the beneficiary not be billed until after the drug has been administered to the beneficiary. CMS is proposing also that the vendor be allowed to bill the beneficiary and his or her third-party insurance after drug administration has been verified by matching the physician claim with the vendor claim using the prescription number, and final payment is made by the Medicare program. **Although we argue that the vendor should NOT have to wait to bill Medicare until the administration claim is processed, we do agree that beneficiaries should be the last link in the chain, and that vendors should not be allowed to bill beneficiaries until after final payment is made by the Medicare program.**

However, we are concerned that beneficiaries are going to be confused by receiving two separate co-payment bills from two separate entities for the drug administration (physician bill) and for the drug itself (vendor bill). We are also concerned about how vendors will handle delivering drugs for patients who are not able to make co-payments and we urge CMS to develop clear rules to govern these situations. Currently, many physicians absorb the cost of copes for indigent patients or guide their patients into charitable Patient Assistance Programs for drugs. CAP vendors should not be able to deny drugs for specific patients based on their historical inability to pay.

- **Drugs that could not be administered on expected date**

If the drug could not be administered to the beneficiary on the expected date of administration, CMS proposes that the physician would notify the vendor and reach an agreement on how to handle the unused drug, consistent with applicable State and Federal law. The notification would also serve to inform the vendor not to submit a claim for the drug. If the vendor and the physician agree that the drug could be maintained in the physician's inventory for administration to another Medicare beneficiary at a later time, the physician would generate a new order form at that time. This process is particularly burdensome and will be a major hindrance for physicians who want to participate in the program, and it should be simplified.

DISPUTE RESOLUTION

CMS's proposed rule is largely silent on resolution of physicians' drug quality and service complaints, but it does say that a physicians' first point of contact for quality related issues will be the vendor and that if the issue is not satisfactorily resolved through the vendor's grievance process, the physician may escalate the matter to the designated carrier immediately. For service related issues, CMS proposes that a physician be allowed to request intervention from the designated carrier, which will attempt to develop solutions that will satisfy both parties. **Physicians will certainly need more details about this process to be able to make informed decisions about whether to participate in the CAP.** Physicians should not be forced to spend their time trying to resolve such issues through a dispute resolution or grievance process that may or may not be resolved to their satisfaction.

CAP PHYSICIAN ELECTION PROCESS

Physicians should be able to choose to opt out of the CAP at any time during their annual election if there are egregious service-related issues. If the objective of CMS in accordance with MMA statutes is to foster physician participation in the CAP program, then certain concessions should be made during the early years of this new and exceedingly complex program. The AUA believes that a one year commitment to the CAP program will serve as a deterrent to urologists considering participation. This has been verified by feedback from our members. **We urge CMS to consider a shorter commitment or a 90-day dropout period for new enrollees in the CAP program.** We realize this may be challenging for vendors in estimating their financial liabilities as a contractor, but it also encourages them to provide better customer service to the physicians and the patients that is program is intended to benefit.

Thank you for considering our comments. If you have any questions or need additional information, please contact Robin Hudson, AUA Manager of Regulatory Affairs, at 410-689-3762 or rhudson@auanet.org.

Sincerely,

Brendan M Fox MD

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President